EXHIBIT 1

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612

Telephone: 949-608-2900
Fax: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

July 13, 2015

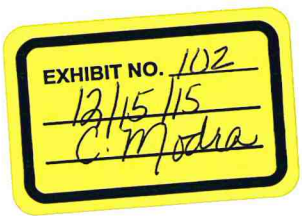
W/L # 27-15

Timothy M. Ring
Chairman and Chief Executive Officer
C.R. Bard Inc.
730 Central Ave.
Murray Hill, NJ 07974

Dear Mr. Ring:

During inspection of your C.R. Bard Inc. facility located at 289 Bay Rd, Queensbury, NY, on October 6, 2014, through November 25, 2014, and during inspection of your Bard Peripheral Vascular facility located at 1625 W. 3rd St., Tempe, AZ, on November 18, 2014, through January 05, 2015, investigators from the United States Food and Drug Administration (FDA) determined that your firm is a specification developer and manufacturer for the Inferior Vena Cava (IVC) filter delivery systems and components, including, but not limited to, the Denali Filter, the Simon Nitinol Filter and Recovery Cone Removal Kit. This warning letter addresses violations found at the Bard Peripheral Vascular facility located at 1625 W. 3rd St., Tempe, AZ and C.R. Bard Inc. facility located at 289 Bay Rd, Queensbury, NY. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body.

We received responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, from Mr. Jason J. Gaede, Vice President Plant Operations, C.R. Bard Inc., Queensbury, NY. We also received responses dated January 26, 2015, February 26, 2015, March 26, 2015, April 24, 2015, and May 22, 2015, from Steve S. Williamson, President, Bard Peripheral Vascular, a Division of C.R. Bard, Tempe, AZ. These were responses to the observations noted on Form FDA 483s, Lists of Inspectional Observations that were issued to you at the close of our inspections. We address your responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:



Adulteration/Misbranding Violations at the Tempe, AZ facility

1. FDA has learned that your firm manufactures the Recovery Cone Removal System, Model RC-15 in the United States without marketing clearance or approval, in violation of the Act. Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body. As explained below, this device is being marketed without the required clearance or approval.

   The Recovery Cone Removal System, Model RC-15 is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g). The Recovery Cone Removal System, Model RC-15 is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k).

   FDA reviewed labeling for the Recovery Cone Removal System, Model RC-15, which revealed that this device is intended to percutaneously remove the Recovery Filter, Recovery G2 Filter and the G2X Filter as indicated. FDA is aware that your firm submitted both in-vitro and in-vivo testing demonstrating the use of the Recovery Cone Removal System, Model RC-15 for removal of the Recovery Filter (K031328), the G2X Filter (K082305), the G2 Express Filter (K080668), and the G2 Filter (K073090). However, the Recovery Cone System, Model RC-15 was not included as part of the clearances for any of the aforementioned IVC filters. Therefore, your firm is marketing the Recovery Cone Removal System, Model RC-15 in the United States without marketing clearance or approval. Percutaneous retrieval systems, such as the Recovery Cone Removal System, Model RC-15, are regulated as manual surgical instruments intended for specialized use within a specific medical specialty, and thus require marketing authorization in order to be legally marketed in the United States.

Your firm has not submitted any correspondence to FDA regarding this violation to date.

2. FDA has also learned that your firm manufactures the Recovery Cone Removal System, Model FBRC in the United States without marketing clearance or approval, in violation of the Act. Under section 201(h) of the Act, 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body. As explained below, this device is being marketed without the required clearance or approval.

   The Recovery Cone Removal System, Model FBRC is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because you do not have an approved

application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. § 360j(g) for the device as described and marketed. The Recovery Cone Removal System, Model FBRC is also misbranded under section 502(o) the Act, 21 U.S.C. 352(o), because you introduced or delivered into interstate commerce for commercial distribution a device with major changes/modifications to the intended use without submitting a new premarket notification to the agency as required by section 510(k), 21 U.S.C. 360(k), and 21 C.F.R. 807.81(a)(3)(ii).

You have listed the Recovery Cone Removal System, Model FBRC as a class I surgical snare under 21 CFR 878.4800. Devices classified under 21 CFR 878.4800 (Surgical Instrument, Manual) are exempt from premarket notification, unless they exceed the limitations on exemptions at 21 CFR 878.9(a). However, there is evidence that the Recovery Cone Removal System, Model FBRC is intended for uses that are different from those of legally marketed devices under 21 CFR 878.4800 (Surgical Instrument, Manual). Devices of this type usually consist of a non-powered, hand-held, or hand-manipulated device that is either reusable or disposable, which are intended to be used in general surgical procedures. Manual surgical instruments intended for specialized uses within a specific medical specialty are classified under regulations separate from 21 CFR 878.4800, depending on the labeled specialized use of the device. However, your firm is marketing the Recovery Cone Removal System, Model FBRC for a specialized intended use, namely percutaneous removal of inferior vena cava filters, specifically your firm's G2X Filter, G2 Express Filter, and G2 Filter. The labeling for the Recovery Cone Removal System, Model FBRC also indicates that your product is intended to percutaneously remove a foreign body.

Based on the above, FDA believes that the Recovery Cone Removal System, Model FBRC is regulated as a percutaneous retrieval system, which is a manual surgical instrument intended for specialized use within a specific medical specialty, cardiovascular surgery. Because there is evidence that the Recovery Cone Removal System, Model FBRC is intended for uses that are different from those of legally marketed devices classified under 21 CFR 878.4800, it exceeds the limitations described in 21 C.F.R. 878.9(a) and is not exempt from premarket notification.

Your firm has not submitted any correspondence to the FDA regarding this violation to date. For a device requiring premarket approval, the notification required by section 510(k) of the Act, 21 U.S.C. § 360(k), is deemed satisfied when a PMA is pending before the agency. 21 C.F.R. 807.81(b). The kind of information you need to submit in order to obtain approval or clearance for your device is described on the Internet at http://www.fda.gov/cdrh/devadvice/3122.html. The FDA will evaluate the information you submit and decide whether your product may be legally marketed.

FDA requests that Bard Peripheral Vascular immediately cease activities that result in the misbranding or adulteration of the Recovery Cone Removal System, Model RC-15 and the Recovery Cone Removal System, Model FBRC, such as the commercial distribution of the devices for the uses discussed above.

Quality System Violations

The inspections also revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection of your Bard Peripheral Vascular Facility located at 1625 W. 3rd St., Tempe, AZ also revealed that the IVC Denali Filter Delivery System is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the devices that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting.

Quality System Regulation Violations at the Tempe, AZ facility and Queensbury, NY facility

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820.198(a). Your current procedures governing complaint investigation activities at your facilities, CQA-STD-24 Standard for Product Complaint Handling Rev. 11 and CQA-STD-55, Standard for Complaint Investigation Process Rev. 01, MP9113, Complaint Investigation Activity Rev. 40, SOPQ0153100, BPV Complaint Handling System, Rev. 18, and SOPQ0700200, Complaint Investigation Procedures, Rev. 15 do not ensure product complaints are adequately evaluated. For example:

    a. Your current procedures governing complaint investigation activities, CQA-STD-24 Standard for Product Complaint Handling Rev. 11, CQA-STD-55, Standard for Complaint Investigation Process Rev. 01, MP9113, Complaint Investigation Activity Rev. 40, SOPQ0153100, BPV Complaint Handling System, Rev. 18, and SOPQ0700200, Complaint Investigation Procedures, Rev. 15 do not include adequate instructions for ensuring that complaints involving a device or device component provided by a supplier are adequately evaluated for root cause of the alleged device failure and that appropriate corrective action is implemented with your suppliers.

    b. Complaint 562535 for a G2 Filter, embolization of a detached filter arm with associated areas of hemorrhage and necrosis in the right lung was filed as a malfunction Medical Device Report [MDR] and should have been filed as a death. The following complaints were filed as malfunctions and should have been filed as serious injuries: Complaint 628924, Eclipse Filter, detached filter limb resulting in pericardial effusion and cardiac catheterization; 574429, G2 Express

Filter, broken filter and surgical intervention; 602904, Denali Jugular System, detached filter arm embedded in IVC wall with filter retrieval; 443237, G2 Filter, detached filter limb in renal vein with IVC wall perforation and blood thinner treatment; 446809, G2 Express Filter, IVC perforation and aneurysm; 454485, G2 Filter, abdominal pain with filter legs protruding through IVC wall and percutaneous removal; 562566, G2 Filter, abdominal pain with filter legs perforating IVC wall, partial retrieval and residual filter leg fragment embedded in IVC wall.

c. Complaints 507112, 507109, 507115, 507252, 507280, 507302, 507311 and 507325 report at least 10 patients who were exposed to scheduled retrieval surgical procedures to remove an IVC filter that were not successful. However, these complaint files do not document sufficient information to allow for adequate complaint investigation and disposition, including, but not limited to, MDR determination. For example, the complaints do not include information regarding prolonged or repeated surgery that may have occurred as a result of failed attempts to remove the filters, information regarding why the filters were scheduled to be removed and potential complications related to leaving them in the patient due to failed removal, and/or if any additional drugs or anesthetics had to be supplied to the patients.

We find that your responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015 and May 6, 2015 from Mr. Jason J. Gaede, Vice President Plant Operations, C.R. Bard Inc., Queensbury, NY and your responses dated January 26, 2015, February 26, 2015, March 26, 2015, April 24, 2015, and May 22, 2015, from Mr. Steve S. Williamson, President, Bard Peripheral Vascular, a Division of C.R. Bard, Tempe, AZ do not adequately address these deficiencies. For example, your January 26, 2015, response states that you made clerical errors and that you opened a CAPA to track training and determination of root cause with corrective and preventive actions. Your response is inadequate and does not assure that your complaint handling system reviews and evaluates complaints adequately. Additionally, the revised complaint procedures provided with your initial responses do not include adequate corrections to complaint investigation procedures with regards to the above stated deficiencies. Your follow-up responses do not address any corrections for complaint handling deficiencies. Your responses also state that all actions have been implemented with respect to the violation and that your firm considers your response to be complete.

Quality System Regulation Violations at the Queensbury, NY facility

4. Failure to validate, with a high degree of assurance and approve according to established procedures, a manufacturing process that cannot be fully verified by subsequent inspection and testing, to ensure the process will continue to meet specifications as required by 21 CFR 820.75(a).

   a. Specifically, IVC filter cleaning, to include removal of chemical processing contaminants, has not been validated for IVC Filters to include Simon Nitinol Filters, Eclipse Filters and Denali Filters. For example, production of Denali

Filters requires the use of several processing agents, including, but not limited to the following: nitric acid, methanol, sulfamic acid solution, thermo quench salt, glycolic acid, citric acid, and/or hydrofluric acid. The cleaning processes for IVC filters are not validated or otherwise verified to demonstrate that the above substances are reduced to acceptable levels during routine processing under worst case conditions. Therefore, your manufacturing process was not validated with a high degree of assurance and approved according to established procedures, nor were the process results fully verified by subsequent inspection and test, as 21 CFR 820.75(a) requires.

b. Your firm's own Process Qualification (PQ) Final Report PRT10-064 Rev A., dated May 29, 2013, states that a 100% inspection plan is necessary for all failed predefined acceptance criteria during process validation. In particular, the PQ Final Report defines process capability acceptance criteria for Denali Filter Part #RM5109000 dimensions of C, D, L, M, G, N, W, F, T, U and the radial force functional test to be a CpK greater than or equal to 1.33 as a requirement to validate the process. Your process qualification failed to meet this predefined acceptance criteria for these filter dimensions and functional test. Therefore, according to your own manufacturing process validation document, 100% inspection for verification of these specifications on each lot of product is required to mitigate your failed process validation. However, your firm has not ensured 100% inspection of dimensions N, W, F, G and M, which lacked validation. Your firm has also not conducted adequate subsequent process validation studies to eliminate this requirement. As a result, your manufacturing process was not validated with a high degree of assurance and approved according to established procedures, nor were the process results fully verified by subsequent inspection and test, as 21 CFR 820.75(a) requires.

We find that your responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, are not adequate for the following reasons:

- With regard to your promised corrections for IVC filter cleaning lacking process validation, we find your response partially adequate. We acknowledge your firm's actions to date associated with the CAPA you opened in response to this observation, GF-CAPA-15-002. We acknowledge that you reviewed 510K submission data for the Denali Filters, conducted recent cytotoxicity testing for Denali Filters and revised your Process Validation procedure, SOP 820.100.6, Rev 43., to specifically include the requirement of validating cleaning processes for components or devices that undergo contact with processing agents. We acknowledge your progress to date validating the cleaning processes for Denali Filters manufactured by both of your suppliers and Simon Nitinol Filters; however, this data will need further review during a follow-up inspection to verify adequacy of actions taken. We also acknowledge your performance of exhaustive extraction testing for the Denali Filters manufactured by one of your suppliers; however, the other supplier of these filters uses a different manufacturing process, processing agents, and equipment. Because of these differences, we recommend that you perform exhaustive extraction testing for Denali Filters manufactured by this supplier to ensure no residuals are present on these devices. Additionally, your firm has stated it is no longer manufacturing the Eclipse Filters as of 9/8/14; however, your firm has not indicated plans

regarding the stored inventory of these devices and continues to market them in the United States. Your response to date does not indicate corrective action for these devices that may still be in inventory and/or may still be distributed.

- With regard to your promised corrections relating to process validation of your Denali Filter Part #RM5109000 dimensions of F, N, W, G and M, we find that your response is not adequate. Your Process Qualification (PQ) Final Report PRT10-064 Rev A., dated May 29, 2013, states that a 100% inspection plan is necessary for all failed predefined acceptance criteria during process validation. In particular, the PQ Final Report defines process capability acceptance criteria for Denali Filter Part #RM5109000 dimensions and/or functional tests of C, D, L, M, G, N, W, F, T, U and Radial Force to be a CpK greater than or equal to 1.33 as a requirement to validate the process. This predefined acceptance criterion was not met. Consequently, your firm conducted a retrospective analysis to change this original process validation criterion. You state your firm retrospectively analyzed data and determined that dimensions N and W may stay on AQL 0.65 limited inspections because the analysis demonstrated a 95/99.9% confidence level. However, your rationale for changing the original process validation acceptance criterion for dimensions N and W is not adequately supported.

Further, you have not been successful at validating the manufacturing process with respect to dimensions F, G and M, which failed predefined acceptance criteria. Your firm has not provided adequate data to support that these dimensions have been 100% inspected for every lot of product manufactured, as required by your firm's own manufacturing process validation document, PQ Final Report PRT10-064. And lastly, the corrective actions proposed as part of CAPA GF-CAPA-15-001 are in progress, and will need verification of implementation upon completion during a future inspection. For these reasons, your responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, are inadequate.

5. Failure to establish and maintain procedures for acceptance of incoming product and to inspect, test or otherwise verify incoming product as conforming to specified requirements as required by 21 CFR 820.80(b).

Specifically, based on your Process Qualification (PQ) Final Report PRT10-064 Rev A., dated May 29, 2013, process capability acceptance criteria of CpK greater than or equal to 1.33 for Denali Filter Part #RM5109000 dimensions C, D, L, M, G, N, W, F, T, U and the radial force functional test were not met. As a result, these dimensions and/or functional tests were to remain on a 100% inspection plan during manufacture at your supplier in order to be accepted into inventory. However, your firm accepted supplier lot numbers #33511-39, #33511-42, #33511-43, #33511-44, #33511-45, #33511-46, #33511-47, #33511-48, #33511-49, #33511-50, #33511-51, #33511-53, #33595-2A-20, #33595-2A-27, #33595-2A-29, #33595-2A-31, #33595-2A-30, #33595-2A-33, #33595-2A-35, #33595-2A-39, #33595-2A-40, #33595-4, and #33771-112 of Denali Filter Part #RM5109000, which your supplier inspected with an AQL 0.65 sampling plan for dimensions N, W, F, G, and M, rather than 100% inspection. Your firm also accepted

supplier lot numbers #33771-129 and #34360-24 of Denali Filter Part #RM5109000, inspected by your supplier with an AQL 0.65 sampling plan for dimensions N and W, rather than 100% inspection. Your procedures for acceptance of incoming product, including Inspection Plan IP #1450935 Rev. 2., were not adequately established and maintained to verify that incoming product conformed to your specified requirements of 100% inspection plan for dimensions N, W, F, G, and M. As a result, you failed to inspect, test or otherwise verify incoming product as conforming to your specified acceptance requirements, as required by 21 CFR 820.80(b).

We find your responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, partially adequate. Your responses do not clarify whether acceptable corrective actions have been taken with the above stated lots of Denali Filter components that lacked 100% inspection of dimensions N, W, F, G, and M to ensure your specified acceptance requirements have been met for these accepted lots. Your response does not contain evidence that the above stated lots indicating an AQL 0.65 sampling plan for dimensions F, G and M were in fact inspected at 100% for F, G and M. Further, your response does not contain evidence that your supplier's AQL 0.65 sampling plan is an adequate inspection, test, or verification of incoming product for dimensions N and W. We acknowledge your firm has opened CAPA GF-CAPA-15-005 to address systemic corrections to this observation; however, outputs of this CAPA are still in progress and will need to be verified during an FDA inspection of your firm.

6. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. In particular, 21 CFR 820.50(a) requires that each manufacturer establish and maintain requirements, including quality requirements, that must be met by suppliers, contractors, and consultants.

   Specifically, your Process Qualification (PQ) Final Report PRT10-064 Rev A., dated May 29, 2013, documented that process capabilities for filter dimensions C, D, L, M, G, N, W, F, T, U and the functional test radial force, as defined under section 7 Acceptance Criteria – Process Qualification of this report, were not met for all dimensions and functional tests. The PQ Final Report states that because the process capabilities were not met, these filter dimensions and functional test should remain on a 100% inspection plan at your supplier until such time that objective evidence indicates process capability has been demonstrated. However, your supplier failed to inspect the product on a 100% inspection plan for filter dimensions N, W, F, G and M, and process capability was not demonstrated through objective evidence. For example, from approximately May 11, 2013 to August 5, 2013, your supplier of Denali Filter Part #RM5109000 provided you with a Certificate of Compliance for supplier lot numbers #33511-39, #33511-42, #33511-43, #33511-44, #33511-45, #33511-46, #33511-47, #33511-48, #33511-49, #33511-50, #33511-51, #33511-53, #33595-2A-20, #33595-2A-27, #33595-2A-29, #33595-2A-31, #33595-2A-30, #33595-2A-33, #33595-2A-35, #33595-2A-39, #33595-

2A-40, #33595-4, and #33771-112. These certificates documented the supplier did not conduct 100% inspection for filter dimensions N, W, F, G and M. Your firm did not begin to address the issue with your supplier until approximately August 5, 2013 during an audit of your supplier, which was after most of these 23 lots were accepted into your inventory and used in the manufacture of finished Denali IVC Filter devices.

In the PQ Final Report PRT10-064 Rev A., your firm establishes purchasing control procedures as required by 21 CFR 820.50(a). These procedures include continued 100% inspection by your supplier for process capabilities that were not met with regards to filter dimensions C, D, L, M, G, N, W, F, T, U and for process capabilities that were not met with respect to the functional test radial force. However, when filter dimensions N, W, F, G, and M failed your established process capabilities, your supplier did not conduct 100% inspection. By failing to maintain adequate supplier control procedures (i.e., by failing to ensure 100% inspection was conducted for failed process capabilities), your firm violated 21 CFR 820.50(a), which requires that manufacturers establish and maintain requirements that must be met by suppliers.

Additionally, when suppliers are placed on Limited Approved status, such as your supplier of the Denali Filter Part #RM5109000, Norman Noble Inc., you do not have adequate instructions in your supplier control procedures, including but not limited to CQA-STA-18 Supplier Performance Management Rev. 05, to re-evaluate suppliers to ensure that the supplier is better able to meet your specifications.

We find that your responses December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, appear adequate, but are still in progress and will need to be verified during an FDA inspection of your firm.

MDR Violations at the Tempe, AZ facility

Our inspection of your Bard Peripheral Vascular facility located at 1625 W. 3rd St., Tempe, AZ also revealed that the Cardiovascular intravascular filter, (IVC Denali Filter Delivery System), is misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information regarding the devices that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant deviations include, but are not limited to:

7. Failure to submit a report to FDA no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that your firm markets has malfunctioned and this device or a similar device that your firm markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 CFR 803.50(a)(2).

For example, Complaint numbers 574292, 427438, 418704, and 416808 describe a malfunction of your firm's device, which is classified as a long term implant. Your firm did not rule out that the reported malfunctions would not be likely to cause or contribute to a death or serious injury, if it were to recur. Therefore, an MDR should have been submitted for each of the referenced complaints.

We reviewed your firm's responses received by the FDA, including the January 26, 2015, response, and conclude the response is not adequate. Your firm did not submit MDRs for the above referenced complaints and failed to justify why such malfunctions would not be likely to cause or contribute to a death or serious injury, if the malfunctions were to recur.

8. Failure to obtain and submit to the FDA information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters; and if unable to submit complete information on a report, failure to provide a statement in your firm's report explaining why required information was incomplete and the steps taken by your firm to obtain the information, as required by 21 CFR 803.50(b)(2) and 21 CFR 803.50(b)(3).

Specifically, your firm submitted 15 MDRs to the FDA, which did not identify the patient's "Age at Time of Event" or "Date of Birth" in Blocks A2 and A4, respectively, of the FDA Form 3500A. In addition, your firm did not include an explanation of why the required information was not provided and the steps taken to obtain such information.

We reviewed your firm's responses received by the FDA, including the January 26, 2015, response, and conclude the response is not adequate. Although the FDA has received supplement reports for some of the MDRs, we have not received supplements for all.

The eMDR Final Rule requiring manufacturers and importers to submit electronic Medical Device Reports (eMDRs) to FDA was published on February 13, 2014. The requirements of this final rule will take effect on August 14, 2015. If your firm is not currently submitting reports electronically, we encourage you to visit the following web link for additional information about the electronic reporting requirements:

http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm107903.htm

If your firm wishes to discuss MDR Reportability criteria or to schedule further communications, it may contact the Reportability Review Team by email at:

ReportabilityReviewTeam@fda.hhs.gov

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality

System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen (15) business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your written response should be sent to the Food and Drug Administration; Attention:

Dr. Raymond W. Brullo
Compliance Officer, Los Angeles District
U. S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

A copy of your written response should also be sent to:

LCDR Catherine M. Beer
Compliance Officer
U. S. Food and Drug Administration
One Winners Circle, Suite 110
Albany, NY 12205

If you have any questions about the content of this letter please contact: Dr. Raymond W. Brullo at (949) 608-2918.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Form FDA 483, Inspectional Observations (FDA 483), issued at the close out of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

for
Alonza E. Cruse, Director
Los Angeles District

Cc:

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bcc:

NYK-DO CB: (Beer/Alexander)
NYK-DO IB: (Frankovic/Terzian/Warner/Izyk)
CFSAN via CMS
HFI-35 (purged) via CMS
Legal file
CMS Case # 453127
EI file C.R. Bard, Queensbury NY (1313046)

LOS-DO DCB file
LOS-DO IB [M. Maxwell, S. Perkins, M. Saale – e-copies]
CMS Case # 453127 [issued version for CO redaction]
Legal File
Factory File
Chron [Brullo]

EXHIBIT 2

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS)
LIABILITY LITIGATION) MD No.: 02641
_____)

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

CONTINUED VIDEOTAPED DEPOSITION OF CHAD MICHAEL MODRA

Phoenix, Arizona
January 20, 2016
9:01 a.m.

REPORTED BY:
Robin L. B. Osterode, RPR, CSR
AZ Certified Reporter No. 50695

(Previously marked Exhibit 102 is attached hereto.)

BY MR. LOPEZ:

Q. Exhibit 102 was marked --

A. Yeah.

Q. Do you have it?

A. Yes, I do.

Q. So we've been talking about this warning letter, and that's what this deposition is about. This is the warning letter, July 13, 2015. Correct?

A. Correct.

Q. And I think last time we agreed that the warning letter is really a letter that involves multiple violations of safety processes, citations, because it actually says that in the warning letter. Right?

A. It does say that.

Q. So why do you suppose they call it a warning letter?

A. They wanted to send a message to the firm that their -- you know, they take these certain elements seriously or they're concerned about these elements of a 483 item form. So that's their vehicle of communicating that to us.

Q. Well, they actually -- I think they include

EXHIBIT 3

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the warning at the end of the letter, if you look at Bates number 242.

A. Yes.

Q. Okay. As a matter of fact, they also make it clear that this letter is not intended to be an all-inclusive list of the violations at your facility?

A. Correct.

Q. And it's your responsibility, meaning the company, to ensure compliance with applicable laws and regulations administered by FDA. Right?

A. Yes.

Q. In other words, FDA is saying that, you know, we didn't come through and do a corner-to-corner, you know, inch-by-inch audit and evaluation of your company; we just did certain things, and we found these violations. And these are not to be considered an all-inclusive list of these violations. Right?

A. That's correct.

Q. And they're telling -- the warning here is that you probably should be looking at other places if you haven't yet, and not rely on FDA to find them?

A. Of course.

Q. And that you should do that irrespective of

EXHIBIT 4

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

To: T. Ring/J. Weiland

From: C. Ganser

Date: August 3, 2005

Subject: IVC Recovery Filter Adverse Events (Migrations/Fractures) – Executive Summary

Following is an adverse event summary of the Bard IVC Recovery Filter for migrations and fractures through 8/2/2005:

Migrations

- 49 filter migrations reported > 2 cm
- 28/49 cases confirmed migration of the filter encased in large thrombi
- 12/49 cases - clot presence was unknown
- 15/28 migrations with confirmed thrombi encasement migrated to the heart
- 16/49 migrations - involved morbidly obese/gastric bypass patients
- 13/49 migrations - death reported
- 11/13 migration associated deaths - massive clot burden reported to have overwhelmed the filter (2 had unknown clot burdens)
- 8/13 migration associated deaths - involved morbidly obese/gastric bypass patients
- 1/13 migration associated deaths - involved Australian patient, information pending
- 1/13 migration associated deaths - involved woman suffering from a sub-arachnoid hemorrhage
- 1/13 migration associated deaths - involved trauma patient (massive head wound)
- 1/13 migration associated deaths - involved a patient post Achilles tendon surgery
- 1/13 migration associated deaths - investigation revealed insufficient data
- 5 pulmonary embolism fatalities, unrelated to migration
- 33,178 units sold as of 8/2/2005
- Estimated 26,542 units placed
- Bard IVC Recovery filter migration rate 0.148% (based on units sold)
- Bard IVC Recovery filter migration related mortality rate 0.039% (based on units sold)

Comparative MAUDE/IMS data for IVC filter fatalities (through Q2 2005):

Rates	Fatalities	Migration
SNF	0.0000%	0.0027%
Recovery	0.0563%	0.1220%
Vena Tech	0.0082%	0.0532%
Greenfield	0.0077%	0.0242%
Bird's Nest	0.0142%	0.0283%
Tulip	0.0149%	0.0277%
TrapEase	0.0147%	0.0152%
OptEase	0.0204%	0.0204%

MAUDE Fatalities are associated with reports associated with migration, caval perforation, caval thrombis, pulmonary embolism, and failed deployment.

Fractures

- 68 reports of filter fractures have been reported to date (rate of 0.205%)
- 25/68 cases involved fragments migrated to the heart/lung (0.075%)
- 4/25 fractures - the patient required surgery to remove detached limb(s)
- No other injuries have been reported
- A literature review reveals that filter fracture is a known complication of IVC filters, with reported rates in the range of 0.05% - 10%

EXHIBIT 5

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

FILTER SALES (IMS Q1 '00 to Q4 '04, + Trend Q1 - Q3 '05)

G2	2,246	* Actual Sales Through November 7, 2005
SNF*	77,572	* Actual Sales through Q3 2005
Recovery*	34,752	* Actual Sales through Q3 2005
Vena Tech	51,265	Need IMS Sales Data - currently based on trend
Greenfield	199,460	Need IMS Sales Data - currently based on trend
Bird's Nest	7,249	Need IMS Sales Data - currently based on trend
Tulip	50,638	Need IMS Sales Data - currently based on trend
TrapEase	192,659	Need IMS Sales Data - currently based on trend
OptEase	16,905	Need IMS Sales Data - currently based on trend
TOTAL	630,500	

DRAFT

Confidential & Privileged

MAUDE DATA THROUGH Q3 2005

Counts	Fatalities	FiltEmb Deaths	Nondeploy AEs	Total Deploy't	Total AEs	Migration	Filter Embolization	Migration	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment	Failed Deployment	Tilted Filter	Other	Detachment of Component(s)
G2 Actual	0	0	4	16	20	1	0	1	3	0	0	0	0	14	0	2	0	0	0
SNF	0	0	26	25	51	1	1	2	7	0	0	2	0	4	10	11	0	0	15
Recovery	19	13	118	22	140	27	19	46	13	0	11	45	0	2	12	8	1	2	0
Vena Tech	4	3	32	21	53	4	23	27	0	0	1	1	1	0	4	16	0	3	0
Greenfield	15	3	85	222	307	14	34	48	10	1	4	9	12	41	130	39	1	12	0
Bird's Nest	1	0	21	9	30	1	1	2	11	0	1	7	0	6	0	3	0	0	0
Tulip	7	2	39	35	74	6	8	14	10	2	2	0	0	5	17	13	4	6	1
TrapEase	28	9	147	33	180	10	19	29	19	62	8	13	0	0	15	18	0	11	0
OptEase	3	0	23	5	28	4	0	4	0	4	4	8	0	2	0	3	0	3	0

Rates	Fatalities	FiltEmb Deaths	Nondeploy AEs	Total Deploy't	Total AEs	Migration	Filter Embolization	Migration	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment	Failed Deployment	Tilted Filter	Other	Detachment of Component(s)
G2 Actual	0.0000%	0.0000%	0.1781%	0.7124%	0.8905%	0.0445%	0.0000%	0.0445%	0.1336%	0.0000%	0.0000%	0.0000%	0.0000%	0.6233%	0.0000%	0.0890%	0.0000%	0.0000%	0.0000%
SNF	0.0000%	0.0000%	0.0335%	0.0322%	0.0657%	0.0013%	0.0013%	0.0026%	0.0090%	0.0000%	0.0000%	0.0026%	0.0000%	0.0052%	0.0129%	0.0142%	0.0000%	0.0000%	0.0193%
Recovery	0.0547%	0.0374%	0.3395%	0.0633%	0.4028%	0.0777%	0.0547%	0.1324%	0.0374%	0.0000%	0.0317%	0.1295%	0.0000%	0.0058%	0.0345%	0.0230%	0.0029%	0.0058%	0.0000%
Vena Tech	0.0078%	0.0059%	0.0624%	0.0410%	0.1034%	0.0078%	0.0449%	0.0527%	0.0000%	0.0000%	0.0020%	0.0020%	0.0000%	0.0000%	0.0078%	0.0312%	0.0000%	0.0059%	0.0000%
Greenfield	0.0075%	0.0015%	0.0428%	0.1113%	0.1539%	0.0070%	0.0170%	0.0241%	0.0050%	0.0005%	0.0020%	0.0045%	0.0060%	0.0206%	0.0652%	0.0196%	0.0005%	0.0060%	0.0000%
Bird's Nest	0.0138%	0.0000%	0.2897%	0.1242%	0.4138%	0.0138%	0.0138%	0.0276%	0.1517%	0.0000%	0.0138%	0.0983%	0.0000%	0.0828%	0.0000%	0.0414%	0.0000%	0.0000%	0.0000%
Tulip	0.0138%	0.0039%	0.0770%	0.0691%	0.1461%	0.0118%	0.0158%	0.0276%	0.0197%	0.0039%	0.0039%	0.0000%	0.0000%	0.0099%	0.0336%	0.0257%	0.0078%	0.0118%	0.0020%
TrapEase	0.0151%	0.0047%	0.0763%	0.0171%	0.0934%	0.0052%	0.0098%	0.0151%	0.0099%	0.0322%	0.0042%	0.0093%	0.0000%	0.0000%	0.0078%	0.0093%	0.0000%	0.0057%	0.0000%
OptEase	0.0177%	0.0000%	0.1381%	0.0286%	0.1656%	0.0237%	0.0000%	0.0237%	0.0000%	0.0237%	0.0237%	0.0473%	0.0000%	0.0118%	0.0000%	0.0177%	0.0000%	0.0177%	0.0000%

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
1		TOTAL	2005	2004	2003	2002	2001	2000	Q4 2005	Q3 2005	Q2 2005	Q1 2005	Q4 2004	Q3 2004	Q2 2004	Q1 2004	Q4 2003	Q3 2003	Q2 2003
2																			
3	TRAPEASE	192,659	27,231	35,889	46,424	41,515	34,274	7,326		8,997	9,121	9,113	8,816	9,572	8,712	8,789	11,155	11,098	11,828
4																			
5	OPTEASE	16,905	6,531	6,671	3,696	7				2,227	2,152	2,151	2,097	1,746	1,834	994	1,794	859	667
6																			
7	GREENFIELD	199,460	16,458	22,645	33,328	37,413	40,155	49,461		5,585	5,480	5,394	5,838	4,963	5,636	6,208	9,236	7,583	8,240
8																			
9	GUNTHER TULIP	50,638	11,097	14,465	16,988	6,722	1,366			3,731	3,751	3,615	3,765	3,588	3,223	3,889	4,888	4,183	4,450
10																			
11	BIRDS NEST FILTER	7,249	538	589	961	1,106	1,492	2,563		184	188	166	180	162	83	164	389	154	146
12																			
13	SNF - Actual	77,572	7,360	11,875	14,040	13,715	13,901	16,681		2,381	2,506	2,473	3,244	2,832	2,960	2,839	3,512	3,489	3,593
14																			
15	RECOVERY - Actual	34,752	12,634	17,976	4,141	1				3,809	4,588	4,237	4,875	4,619	4,300	4,182	2,280	1,047	644
16																			
17	VENA TECH	51,265	7,081	9,714	10,042	9,322	4,856	10 250		2,383	2,337	2,361	2,448	2,211	2,581	2,474	2,256	2,924	2,167
18																			
19																			
20																			
21	ALL PRODUCTS	630,500	59,634	119,824	129,620	109,801	96,044	86,281			30,123	29,511	31,263	29,693	29,329	29,539	35,510	31,337	31,735
22																			
23	NON RECOVERY PRODUCTS	595,748	50,809	101,848	125,479	109,800	96,044	86,281			25,535	25,274	26,388	25,074	25,029	25,357	33,230	30,290	31,091
24																			
25																			
26	No data available (based on last 4 quarters' trend)																		
27																			
28																			
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	T	U	V	W	X	Y	Z	AA	AB	AC	AD	AE	AF
1	Q1 2003	Q4 2002	Q3 2002	Q2 2002	Q1 2002	Q4 2001	Q3 2001	Q2 2001	Q1 2001	Q4 2000	Q3 2000	Q2 2000	Q1 2000
2													
3	12,343	11,744	10,875	9,296	9,600	11,618	8,785	7,873	5,998	4,931	2,395		
4													
5	376	7											
6													
7	8,269	9,592	8,862	8,954	10,005	10,257	9,839	9,642	10,417	10,117	11,095	13,041	15,208
8													
9	3,467	2,018	1,566	2,085	1,053	924	442						
10													
11	272	384	157	297	268	423	194	270	605	358	567	711	927
12													
13	3,446	3,637	3,343	3,418	3,317	3,456	3,271	3,467	3,707	3,943	3,665	4,534	4,539
14													
15	170	1	1										
16													
17	2,695	2,812	2,422	2,312	1,776	1,338	1,299	917	1,302	1,675	2,092	2,784	3,699
18													
19													
20													
21	31,038	30,195	27,225	26,362	26,019	28,016	23,830	22,169	22,029	21,024	19,814	21,070	24,373
22													
23	30,868	30,194	27,225	26,362	26,019	28,016	23,830	22,169	22,029	21,024	19,814	21,070	24,373
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	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment	Failed Deployment	Tilted Filter	Other	Caval Penetration	Detachment of Component(s)
2	0	1	0	3	0	0	0	0	14	0	2	0	0	0	0
3															
4	**ACTUAL COMPLAINT DATA THROUGH NOVEMBER 7, 2005**														
5															
6	Company	Device	Date	Source	Complaint #	Failure	Location	Death?	FiltEmb death?	0					
7	BPV	G2	9/23/2005	TrackWise	59230	Difficult to Deploy									
8	BPV	G2	10/5/2005	TrackWise	60609	Failed Deployment									
9	BPV	G2	10/18/2005	TrackWise	61886	Caval Perforation									
10	BPV	G2	10/26/2005	TrackWise	62625	Misplaced Deployment									
11	BPV	G2	10/26/2005	TrackWise	62649	Difficult to Deploy									
12	BPV	G2	10/26/2005	TrackWise	62661	Misplaced Deployment									
13	BPV	G2	10/28/2005	TrackWise	62951	Difficult to Deploy									
14	BPV	G2	10/28/2005	TrackWise	62992	Misplaced Deployment									
15	BPV	G2	10/28/2005	TrackWise	62993	Misplaced Deployment									
16	BPV	G2	10/28/2005	TrackWise	62994	Misplaced Deployment									
17	BPV	G2	10/28/2005	TrackWise	62995	Misplaced Deployment									
18	BPV	G2	10/28/2005	TrackWise	62996	Misplaced Deployment									
19	BPV	G2	10/28/2005	TrackWise	62997	Difficult to Deploy									
20	BPV	G2	10/28/2005	TrackWise	62998	Difficult to Deploy									
21	BPV	G2	10/28/2005	TrackWise	62999	Misplaced Deployment									
22	BPV	G2	10/28/2005	TrackWise	63000	Misplaced Deployment									
23	BPV	G2	10/28/2005	TrackWise	63001	Difficult to Deploy									
24	BPV	G2	10/28/2005	TrackWise	63002	Misplaced Deployment									
25	BPV	G2	11/1/2005	TrackWise	63225	Misplaced Deployment									
26	BPV	G2	11/2/2005	TrackWise	63399	Misplaced Deployment									
27	BPV	G2	11/7/2005	TrackWise	63855	Migration	Mig + Perf								
28	BPV	G2	11/7/2005	TrackWise	63855	Caval Perforation	Mig + Perf								
29	BPV	G2	11/7/2005	TrackWise	63874	Misplaced Deployment									
30	BPV	G2	11/7/2005	TrackWise	63875	Misplaced Deployment									
31	BPV	G2	11/7/2005	TrackWise	63920	Out-of-box failure									
32	BPV	G2	8/2/2005	TrackWise	53884	Failed Deployment									
33	BPV	G2	10/24/2005	TrackWise	62332	Caval Perforation									
34	BPV	G2	10/24/2005	TrackWise	62345	Missing Components									
35	BPV	G2													
36	BPV	G2													
37	BPV	G2													
38	BPV	G2													
39	BPV	G2													
40	BPV	G2													
41	BPV	G2													
42	BPV	G2													
43	BPV	G2													
44	BPV	G2													
45	BPV	G2													
46	BPV	G2													
47	BPV	G2													

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment	Failed Deployment	Tilted Filter	Other
2	0	1	1	7	0	0	2	0	4	10	11	0	0
3													
4													
5													
6	Company	Device	Date	Source	FDA #	Failure	Location	Death?	FiltEmb death?	0			
7	BPV	SIMON NITIONOL VENA	5/2/2005	KMJ	599074	Caval Perforation							
8	BPV	SIMON NITINOL FILTER	4/6/2005	KMJ	590761	Failed Deployment							
9	BPV	SIMON NITINOL FILTER	3/30/2005	KMJ	587919	Misplaced Deployment							
10	BPV	SIMON NITINOL FILTER	3/30/2005	KMJ	587882	N/A - Sales Rep issue							
11	BPV	SIMON NITIONOL FILTE	3/28/2005	KMJ	586963	Partial Deployment	Filter & part of catheter iimpanted						
12	BPV	SIMON NITNOLFILTER-F	3/16/2005	KMJ	584469	Partial Deployment	"6th Foot" did not open						
13	BPV	SIMON NITINOL FILTER	1/24/2005	KMJ	571075	Partial Deployment	Twisted Legs						
14	BPV	SIMON NITINOL VENA C	1/5/2005	KMJ	565692	Partial Deployment	Crossed Legs						
15	BPV	SIMON NITINOL VENA C	11/29/04	BPV	557650	Failed Deployment							
16	BPV	SIMON NITINOL FILTER	11/15/04	BPV	558935	Failed Deployment							
17	BPV	SIMON NITINOL VENA C	08/20/04	BPV	541700	Misplaced Deployment	upside down deployment						
18	BPV	SIMON NITINOL VENA C	06/11/04	BPV	529838	Caval Perforation							
19	BPV	SIMON NITINOL FILTER	03/10/04	BPV	515514	Caval Perforation							
20	BPV	SIMON NITINOL FILTER	01/30/04	BPV	517796	Detachment of Component(s)	Marker Bands						
21	BPV	SIMON NITINOL FILTER	01/20/04	BPV	515079	Misplaced Deployment							
22	BPV	SIMON NITINOL FILTER	12/23/03	DJU	506286	Filter Fracture	Leg in Renal Vein						
23	BPV	SIMON NITINOL FILTER	12/23/03	JWL	503017	Filter embolization	Migration (Rt Heart)/	Deployed Upside-down					
24	BPV	SIMON NITINOL FILTER	12/12/03	BPV	504208	Detachment of Component(s)							
25	BPV	SIMON NITINOL VENA C	09/29/03	BPV	487339	Partial Deployment							
26	BPV	SIMON NITINOL FILTER	09/29/03	DJU	487339	Migration	Movement 1 cm						
27	BPV	SIMON NITINOL FILTER	04/11/03	BPV	453965	Detachment of Component(s)	Marker Bands						
28	BPV	SIMON NITINOL FILTER	04/02/03	BPV	452201	Detachment of Component(s)	Marker Bands						
29	BPV	SIMON NITINOL FILTER	03/13/03	BPV	448182	Detachment of Component(s)	Marker Bands						
30	BPV	2320A-S/SNF ANTECUBI	01/17/03	BPV	438877	Detachment of Component(s)	Marker Bands						
31	BPV	2120F-S/SNF FEMORAL	11/18/02	BPV	429497	Failed Deployment	Legs Twisted						
32	BPV	2120F-S/SNF FEMORAL	11/18/02	BPV	429330	Failed Deployment	Legs Twisted						
33	BPV	2120F-S/SNF FEMORAL	11/18/02	BPV	429328	Failed Deployment	Legs Twisted						
34	BPV	2220J-S/SNF-JUGULAR	11/08/02	BPV	428025	Filter Fracture	Filter Fracture						
35	BPV	2120F-S/SNF FEMORAL	08/20/02	BPV	412957	Partial Deployment	Legs did not open						
36	BPV	3220J-NITINOL JUGULA	07/18/02	BPV	406553	Detachment of Component(s)	Marker Bands						
37	BPV	SIMON NITINOL FILTER	06/21/02	BPV	401126	Detachment of Component(s)	Marker Bands						
38	BPV	SIMON NITINOL FILTER	06/17/02	BPV	400874	Caval Perforation							
39	BPV	SIMON NITINOL FILTER	05/22/02	DJU	396361	Detachment of Component(s)	Marker Bands						
40	BPV	SIMON NITINOL FILTER	05/13/02	BPV	394027	Detachment of Component(s)	Marker Bands						
41	BPV	SIMON NITINOL FILTER	04/15/02	BPV	388439	Caval Perforation							
42	BPV	SIMON NITINOL FILTER	04/02/02	BPV	386983	Detachment of Component(s)	Marker Bands						
43	BPV	SIMON NITINOL FILTER	03/22/02	BPV	384797	Caval Perforation							
44	BPV	SIMON NITINOL FILTER	03/05/02	BPV	381558	Failed Deployment	Hooks Stuck						
45	BPV	SIMON NITINOL FILTER	03/05/02	BPV	380816	Caval Perforation							
46	BPV	SIMON NITINOL FILTER	02/11/02	BPV	377174	Failed Deployment	Hooks Stuck						
47	BPV	SIMON NITINOL FILTER	02/11/02	DJU	377169	Misplaced Deployment	Hooks Stuck						

	A	B	C	D	E	F	G	H	I	J	K	L	M
48	BPV	SIMON NITINOL FILTER	06/20/01	BPV	338490	Partial Deployment							
49	BPV	SIMON NITINOL FILTER	06/20/01	BPV	338470	Partial Deployment							
50	BPV	SIMON NITINOL FILTER	05/14/01	BPV	333322	Partial Deployment							
51	BPV	SIMON NITINOL FILTER	05/14/01	BPV	333319	Failed Deployment	Legs Twisted						
52	BPV	SIMON NITINOL FILTER	03/23/01	BPV	321923	Detachment of Component(s)	Marker Bands						
53	BPV	SIMON NITINOL FILTER	11/28/00	BPV	306765	Detachment of Component(s)	Marker Bands						
54	BPV	SIMON NITINOL FILTER	10/16/00	BPV	300860	Detachment of Component(s)	Marker Bands						
55	BPV	SIMON NITINOL FILTER	10/13/00	BPV	300150	Detachment of Component(s)	Marker Bands						
56	BPV	SIMON NITINOL FILTER	08/21/00	BPV	292233	Failed Deployment	Hooks Stuck						
57	BPV	SIMON NITINOL FILTER	05/19/00	BPV	278519	Partial Deployment							
58	BPV	SIMON NITINOL FILTER	04/13/00	BPV	273932	Failed Deployment	Failed Deployment						
59	BPV												
60	BPV												
61	BPV												
62	BPV												
63	BPV												
64	BPV												
65	BPV												
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96	BPV												
97	BPV												
98	BPV												
99	BPV												

	A	B	C	D	E	F	G	H	I	J
1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment
2	19	27	19	13	0	11	45	0	2	12
3										
4										
5										
6	Company	Device	Date	Source	FDA #	Failure	Comments	Death	Filter Emb death?	13
7	BPV	BARD	9/18/2005	KMJ	636272	Caval Perforation	may be duplicate of 636277			
8	BPV	RECOVERY FILTER	9/13/2005	KMJ	636277	Caval Perforation				
9	BPV	RECOVERY FILTER	9/12/2005	KMJ	634437	Pulmonary Embolism	moved up "one vertebra"			
10	BPV	RECOVERY FILTER	9/8/2005	KMJ	633930	Migration	4 cm to iliac vein			
11	BPV	RECOVERY FILTER	9/7/2005	KMJ	633727	Migration	to heart @ implant			
12	BPV	RECOVERY FILTER	9/1/2005	KMJ	633205	Filter Fracture	633205: Migr & 1 Detached Leg			
13	BPV	RECOVERY FILTER	9/1/2005	KMJ	633205	Filter Embolization	to tricuspid valve w/ heavy clot burden	Death	1	
14	BPV	RECOVERY VENA CAVA F	8/24/2005	KMJ	631194	Migration	to tricuspid valve w/ clot			
15	BPV	RECOVERY FILTER	8/9/2005	KMJ	627651	Filter Fracture	Detached partial leg or hook?			
16	BPV	RECOVERY FILTER	8/1/2005	KMJ	624371	Failed Deployment				
17	BPV	RECOVERY FILTER	7/29/2005	KMJ	631071	Misplaced Deployment				
18	BPV	RECOVERY FILTER	7/27/2005	KMJ	629054	Filter Fracture	1 Arm - caught in filter & removed			
19	BPV	RECOVERY FILTER	7/14/2005	KMJ	621545	Migration	to heart w/ clot burden			
20	BPV	RECOVERY FILTER	7/14/2005	KMJ	621543	Filter Fracture	2 Arms			
21	BPV	BARD SYSTEMS	7/12/2005	KMJ	621074	= 619697	duplicate			
22	BPV	RECOVERY FILTER	7/12/2005	KMJ	621078	Filter Fracture	1 Arm in lung			
23	BPV	BARD 'RECOVERY' FILT	7/8/2005	KMJ	620484	Migration	to heart w/ multiple clots			
24	BPV	RECOVERY FILTER	7/7/2005	KMJ	620888	Filter Fracture	1 Arm in cava wall - removed successfully			
25	BPV	RECOVERY FILTER	7/7/2005	KMJ	620897	Filter Fracture	1 Arm & 2 Hooks			
26	BPV	RECOVERY FILTER	7/7/2005	KMJ	620859	Filter Fracture	2 Arms (rt atrium & pulm artery)			
27	BPV	BARD SYSTEMS	7/1/2005	KMJ	619697	Filter Fracture	1 Arm in lower lobe/pulm artery branch			
28	BPV	RECOVERY FILTER	7/1/2005	KMJ	619081	Migration	Hepatic/right atrium junction			
29	BPV	RECOVERY FILTER	7/1/2005	KMJ	616355	Migration	Rt atrium w/ clot burden			
30	BPV	RECOVERY FILTER	6/16/2005	KMJ	615340	Filter Embolization	Filter & clot in right atrium	Death	1	
31	BPV	RECOVERY FILTER	6/15/2005	KMJ	614686	Filter Embolization	Both pulm arteries, filter w/massive clot	Death	1	
32	BPV	RECOVERY FILTER	6/15/2005	KMJ	614668	Migration	5cm into the hepatic ivc			
33	BPV	RECOVERY FILTER	6/13/2005	KMJ	614127	Filter Embolization	Filter & clot in rt atrium	Death	1	
34	BPV	BARD RECOVERY	6/13/2005	KMJ	614168	Migration				
35	BPV	RECOVERY FILTER	6/3/2005	KMJ	611395	Pulmonary Embolism				
36	BPV	RECOVERY FILTER	6/3/2005	KMJ	618010	Filter Fracture				
37	BPV	BARD RECOVERY FILTER	5/26/2005	KMJ	608450	Filter Fracture	3cm into Renals + 4 arms detached			
38	BPV	BARD RECOVERY FILTER	5/26/2005	KMJ	608450	Migration	3cm into Renals + 4 arms detached			
39	BPV	RECOVERY FILTER	5/23/2005	KMJ	597752	Duplicate	Migration - Distal the right atrium			
40	BPV	RECOVERY FILTER	5/10/2005	KMJ	603617	Filter Fracture	1 hook missing			
41	BPV	BARD RECOVERY FILTER	5/3/2005	KMJ	598730	Filter Fracture	1 arm in right pulmonary artery			
42	BPV	RECOVERY FILTER	4/26/2005	KMJ	597752	Migration	Distal the right atrium			
43	BPV	RECOVERY FILTER	4/26/2005	KMJ	598730	Filter Fracture	1 arm in right pulmonary artery			
44	BPV	BARD IVC FILTER	4/14/2005	KMJ	593418	Duplicate	Duplicate in database			
45	BPV	BARD IVC FILTER	4/14/2005	KMJ	593418	Filter Fracture				
46	BPV	RECOVERY FILTER	4/13/2005	KMJ	592511	Partial Deployment	Twisted legs			
47	BPV	RECOVERY FILTER	4/13/2005	KMJ	592547	Filter Fracture	Limb in lung			
48	BPV	RECOVERY FILTER	4/12/2005	KMJ	592748	Filter Fracture	2 arms - renal vein & iliac			
49	BPV	RECOVERY FILTER	4/12/2005	KMJ	591237	Migration	Tip in right artium			
50	BPV	RECOVERY FILTER	4/12/2005	KMJ	592730	Failed Deployment				

	A	B	C	D	E	F	G	H	I	J
51	BPV	RECOVERY FILTER	4/12/2005	KMJ	592740	Caval Perforation				
52	BPV	RECOVERY FILTER	4/7/2005	KMJ	590300	Caval Perforation				
53	BPV	RECOVERY FILTER	4/4/2005	KMJ	588407	Pulmonary Embolism		Death		
54	BPV	RECOVERY FILTER	3/25/2005	KMJ	587269	Filter Fracture				
55	BPV	RECOVERY FILTER	3/25/2005	KMJ	569852	Tilted Filter				
56	BPV	RECOVERY FILTER	3/15/2005	KMJ	585163	Partial Deployment	Twisted Legs			
57	BPV	RECOVERY FILTER	3/15/2005	KMJ	575175	Filter Fracture				
58	BPV	RECOVERY FILTER	3/14/2005	KMJ	584484	Filter Fracture				
59	BPV	BARD	3/14/2005	KMJ	584473	Filter Fracture				
60	BPV	BARD RECOVERY IVC FI	3/14/2005	KMJ	581678	Filter Fracture				
61	BPV	RECOVERY FILTER	3/10/2005	KMJ	583349	Partial Deployment	Twisted Legs			
62	BPV	RECOVERY FILTER	3/7/2005	KMJ	580296	Pulmonary Embolism		Death		
63	BPV	RECOVERY FILTER	3/4/2005	KMJ	582383	Filter Fracture				
64	BPV	RECOVERY FILTER	3/4/2005	KMJ	582362	Filter Fracture				
65	BPV	RECOVERY FILTER	3/3/2005	KMJ	581426	Misplaced Deployment	accessory vein			
66	BPV	RECOVERY FILTER	2/25/2005	KMJ	580062	Filter Fracture				
67	BPV	RECOVERY FILTER	2/25/2005	KMJ	578634	Pulmonary Embolism		Death		
68	BPV	BARD	2/15/2005	KMJ	575244	= 567210	Duplicate of 567210			
69	BPV	RECOVERY FILTER	2/9/2005	KMJ	572544	Pulmonary Embolism		Death		
70	BPV	RECOVERY FILTER	2/8/2005	KMJ	574995	Migration	5 cm movement w/ clot			
71	BPV	RECOVERY FILTER	2/8/2005	KMJ	572279	Migration	right atrium			
72	BPV	UNKNOWN BRAND NAME	1/31/2005	KMJ	584859	Filter Fracture				
73	BPV	RECOVERY FILTER	1/31/2005	KMJ	574154	Filter Fracture	Fracture + Migration			
74	BPV	RECOVERY FILTER	1/31/2005	KMJ	574154	Migration	Fracture + Migration			
75	BPV	BARD RECOVERY FILTER	1/31/2005	KMJ	570337	Filter Fracture				
76	BPV	RECOVERY FILTER	1/31/2005	KMJ	569583	Migration	3 cm movement w/ clot			
77	BPV	RECOVERY FILTER	1/28/2005	KMJ	571941	Migration	2 cm movement w/ 10cm of clot			
78	BPV	RECOVERY FILTER	1/24/2005	KMJ	571084	Filter Fracture				
79	BPV	RECOVERY FILTER	1/19/2005	KMJ	569799	Partial Deployment	legs opened asymmetrically			
80	BPV	RECOVERY FILTER	1/18/2005	KMJ	570361	Filter Fracture				
81	BPV	RECOVERY FILTER	1/14/2005	KMJ	569850	Filter Fracture				
82	BPV	RECOVERY FILTER	1/14/2005	KMJ	569848	Partial Deployment	Twisted Legs			
83	BPV	RECOVERY FILTER	1/13/2005	KMJ	587274	Filter Fracture				
84	BPV	BARD	1/13/2005	KMJ	567210	Filter Fracture	arm in pulmonary artery at autopsy	Death		
85	BPV	RECOVERY FILTER	1/12/2005	KMJ	568356	Filter Fracture				
86	BPV	RECOVERY FILTER	1/6/2005	KMJ	565461	Failed Deployment	Arms and Legs did not open			
87	BPV	VENA CAVA FILTER	1/6/2005	KMJ	564519	= 567210	Duplicate of 567210			
88	BPV	RECOVERY FILTER	1/5/2005	KMJ	565157	Failed Deployment	Legs did not open			
89	BPV	RECOVERY FILTER	1/5/2005	KMJ	564369	Filter Fracture				
90	BPV	RECOVERY FILTER	1/5/2005	KMJ	564354	Pulmonary Embolism				
91	BPV	RECOVERY FILTER	12/22/2004	BPV	565413		Duplicate			
92	BPV	RECOVERY FILTER	12/22/2004	BPV	561581	Caval Perforation				
93	BPV	RECOVERY FILTER	12/21/2004	BPV	561390	Migration				
94	BPV	RECOVERY FILTER	12/15/2004	BPV	560531	Filter Embolization		Death	1	
95	BPV	RECOVERY FILTER	12/14/2004	BPV	560255	Partial Deployment	Twisted Legs			
96	BPV	RECOVERY FILTER	12/14/2004	BPV	560255	Partial Deployment	Twisted Legs			
97	BPV	BARD RECOVERY FILTER	12/9/2004	BPV	562812		Duplicate			
98	BPV	BARD RECOVERY FILTER	12/9/2004	BPV	562817	Filter Embolization				
99	BPV	RECOVERY FILTER	12/8/2004	BPV	558963	Partial Deployment	Twisted Legs			
100	BPV	RETRIEVABLE GREENFIE	12/7/2004	BPV	560997	Filter Fracture				
101	BPV	RECOVERY FILTER	12/1/2004	BPV	557639	Caval Perforation				
102	BPV	RECOVERY FILTER	11/10/2004	BPV	554903	Migration	T-12			

	A	B	C	D	E	F	G	H	I	J
103	BPV	BARD RECOVERY FILTER	11/4/2004	BPV	557688	Filter Embolization		Death	1	
104	BPV	RECOVERY FILTER	10/26/2004	BPV	552526	Filter Fracture				
105	BPV	RECOVERY FILTER	10/14/2004	BPV	549338	Filter embolization	Rt Heart	Death	1	
106	BPV	RECOVERY FILTER	10/14/2004	BPV	549017	Filter Embolization	Heart			
107	BPV	RECOVERY FILTER	10/14/2004	BPV	549017	Failed Deployment	Did not Open			
108	BPV	BARD RECOVERY IVC FI	10/5/2004	BPV	557154	Migration	Caudal - 4cm			
109	BPV	BARD RECOVERY IVC FI	10/5/2004	BPV	557154	Filter Fracture	Arm			
110	BPV	BARD RECOVERY IVC FI	10/5/2004	BPV	556875		Same as 557154			
111	BPV	RECOVERY FILTER	10/1/2004	BPV	547044	Migration				
112	BPV	RECOVERY FILTER	10/1/2004	BPV	547044	Filter Fracture	Hook			
113	BPV	RECOVERY FILTER	9/21/2004	JWL	545303	Filter Embolization	intrahepatic IVC	Death	1	
114	BPV	RECOVERY FILTER	9/21/2004	BPV	545298	Caval Perforation				
115	BPV	RECOVERY FILTER	9/21/2004	JWL	545283	Caval Perforation	Removed, fine			
116	BPV	RECOVERY FILTER	9/10/2004	BPV	543326	Caval Perforation				
117	BPV	RECOVERY FILTER	9/9/2004	BPV	543154	Failed Deployment	Crossed Legs			
118	BPV	RECOVERY FILTER	9/9/2004	BPV	543080	= 545130				
119	BPV	RECOVERY FILTER	9/9/2004	BPV	543075	Failed Deployment	Crossed Legs			
120	BPV	RECOVERY FILTER	9/9/2004	BPV	543065	Pulmonary embolism	6-8cm			
121	BPV	RECOVERY FILTER	9/9/2004	BPV	543065	Migration	6-8cm			
122	BPV	RECOVERY FILTER	8/30/2004	BPV	541694	Other	Pain			
123	BPV	RECOVERY FILTER	8/30/2004	JWL	541690	Filter embolization	right atrium			
124	BPV	RECOVERY FILTER	8/26/2004	JWL	541353	Filter embolization	heart	Death	1	
125	BPV	RECOVERY FILTER	8/23/2004	JWL	540532	Filter embolization	heart, placed into large cava			
126	BPV	RECOVERY FILTER	8/19/2004	BPV	540258	Caval Perforation				
127	BPV	BARD-RECOVERY FILTER	8/13/2004	BPV	545130	Filter Fracture				
128	BPV	RECOVERY FILTER	8/5/2004	BPV	538204	migration	L3 to T9/10			
129	BPV	RECOVERY FILTER	8/5/2004	BPV	538201	migration	L2 to T12			
130	BPV	RECOVERY FILTER	8/4/2004	BPV	538046	Caval perforation				
131	BPV	FEMORAL RECOVERY FIL	7/30/2004	JWL	538589	= 541353	Heart			
132	BPV	RECOVERY FILTER	7/28/2004	BPV	537411	Filter Fracture				
133	BPV	RECOVERY FILTER	7/14/2004	JWL	534603	= 534597	duplicate of 534597			
134	BPV	BARD	7/14/2004	JWL	534597	Filter embolization	right ventricle	Death	1	
135	BPV	RECOVERY FILTER	7/7/2004	BPV	533379	Other	Pain			
136	BPV	RECOVERY FILTER	6/21/2004	BPV	541295	Filter Fracture	retrieval attempts caused fracture?			
137	BPV	RECOVERY FILTER	6/21/2004	JWL	531130	Filter embolization	tricuspid valve			
138	BPV	RECOVERY FILTER	6/14/2004	JWL	530079	Filter embolization	heart	Death	1	
139	BPV	RECOVERY FILTER	6/4/2004	JWL	531446	= 525383	duplicate of 525383			
140	BPV	BARD PERIPHERAL VASC	6/1/2004	JWL	528008	= 530079	duplicate of 530079			
141	BPV	RECOVERY VENA CAVA	5/24/2004	BPV	526245	Filter Fracture				
142	BPV	RECOVERY FILTER	5/21/2004	BPV	526110	Pulmonary embolism	4cm + PE			
143	BPV	RECOVERY FILTER	5/21/2004	BPV	526110	Migration	4cm + PE			
144	BPV	RECOVERY FILTER	5/12/2004	JWL	525383	Filter embolization	right ventricle	Death	1	
145	BPV	CR BARD	4/28/2004	JWL	522655	= 525383	duplicate of 525383			
146	BPV	RECOVERY FILTER	4/16/2004	BPV	521172	Caval perforation				
147	BPV	RECOVERY FILTER	3/31/2004	BPV	542132	Partial Deployment	Crossed Legs			
148	BPV	RECOVERY FILTER	3/31/2004	BPV	541621	Partial Deployment				
149	BPV	RECOVERY FILTER	3/18/2004	BPV	536423	Filter Fracture				
150	BPV	RECOVERY FILTER	3/18/2004	BPV	516863	Filter embolization	right atrium/doctor pushed it there	Death	1	
151	BPV	BARD RECOVERY FILTER	3/8/2004	JWL	515237	Filter embolization	right atrium			
152	BPV	RECOVERY FILTER	3/2/2004	BPV	514355	Pulmonary Embolism	Filter tilted			
153	BPV	BARD	2/17/2004	JWL	511801	= 515237	duplicate of 515237			
154	BPV	RECOVERY FILTER	2/15/2004	BPV	513064	Partial Deployment	Crossed Legs			

	A	B	C	D	E	F	G	H	I	J
155	BPV	RECOVERY FILTER	2/10/2004	BPV	523879	Failed Deployment	Crossed Legs			
156	BPV	RECOVERY FILTER	1/21/2004	BPV	511593	Filter Fracture				
157	BPV	RECOVERY FILTER	12/23/2003	JWL	503023	Migration				
158	BPV	RECOVERY FILTER	12/12/2003	BPV	504579	Partial Deployment	Crossed Legs			
159	BPV	RECOVERY FILTER	11/17/2003	BPV	498388	Migration	Migration (Supra-renal)			
160	BPV	RECOVERY FILTER	10/1/2003	BPV	487899	Caval perforation				
161	BPV	RECOVERY FILTER	9/15/2003	BPV	484249	Pulmonary Embolism		Death		
162										
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169										
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	A	B	C	D	E	F	G	H	I
1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment
2	4	4	23	0	0	1	1	1	0
3									
4									
5									
6	Company	Device	Date	Source	FDA #	Failure	Location	Death?	FilteEmb death?
7	B. BRAUN MEDICAL	VENA TECH	8/19/2005	KMJ	628618	Migration	Did not open at implant, migrated to heart/lungs		
8	B. BRAUN MEDICAL	VENA TECH	8/5/2005	KMJ	624755	Failed Deployment	Legs would not open		
9	B. BRAUN MEDICAL	VENA TECH	7/27/2005	KMJ	623284	Failed Deployment	Did not open		
10	B. BRAUN MEDICAL, IN	VENA TECH	6/24/2005	KMJ	617223	Failed Deployment	Deployed in pt's gonadel vein		
11	B. BRAUN MEDICAL, IN	VENA TECH	6/23/2005	KMJ	617110	Failed Deployment	Filter then turned upside down		
12	B. BRAUN MEDICAL, IN	VENA TECH	6/13/2005	KMJ	614111	Failed Deployment			
13	B. BRAUN MEDICAL, IN	VENA TECH	6/13/2005	KMJ	613670	Filter embolization	Pulmonary Artery	Death	1
14	B. BRAUN MEDICAL, IN	VENA TECH	6/8/2005	KMJ	612832	Failed Deployment	Did not open & then tilted		
15	B. BRAUN MEDICAL, IN	VENA TECH	5/31/2005	KMJ	610574	Duplicate = 586485			
16	B. BRAUN MEDICAL, IN	VENA-TECH LP	4/22/2005	KMJ	596302	Failed Deployment	Surgery required to remove filter		
17	B. BRAUN MEDICAL, IN	BRAUN VENA-TECH FILT	3/23/2005	KMJ	586485	Migration	Filter & mass in rt atrium		
18	B. BRAUN MEDICAL, IN	VENA TECH	12/03/04	BPV	557804	Filter embolization	RA		
19	B. BRAUN MEDICAL, IN	VENA TECH	10/07/04	BPV	548359	Filter Tilt			
20	B. BRAUN MEDICAL, IN	VENA TECH	10/07/04	BPV	548359	Migration			
21	B. BRAUN MEDICAL, INC	VENA TECH	08/19/04	BPV	540178	guidewire entrapment			
22	B. BRAUN MEDICAL, INC	VENA TECH	08/02/04	JWL	539352	Filter embolization	PA		
23	B. BRAUN MEDICAL, INC	B. BRAUN	06/29/04	JWL	537548	Filter embolization	PA		
24	B. BRAUN MEDICAL, INC	VENA TECH	06/16/04	JWL	530752	Partial deployment			
25	B. BRAUN MEDICAL, INC	VENA TECH LP	05/14/04	JWL	525261	Failed Deployment			
26	B. BRAUN MEDICAL, INC	VENA TECH	01/08/04	BPV	505702	Failed Deployment			
27	B. BRAUN MEDICAL, INC	VENA TECH LP	12/24/03	JWL	502789	Filter embolization	Migration (RA)/Partial Deployment		
28	B. BRAUN MEDICAL, INC	VENA CAVA FILTER	12/23/03	BPV	503348	Other			
29	B. BRAUN MEDICAL, INC	VENA TECH IVC FILTER	12/03/03	JWL	502269	Filter embolization	Migration (PA)		
30	B. BRAUN MEDICAL, INC	VENA TECH LP	10/09/03	BPV	488892	Failed Deployment			
31	B. BRAUN MEDICAL, INC	VENA CAVA FILTER SYS	10/03/03	JWL	487738	Filter embolization	Migration (Lung)/Partial Deployment		
32	B. BRAUN MEDICAL, INC	VENA TECH	05/12/03	JWL	459982	Filter embolization	Migration (Pulmonary Artery)/Partial Deployment	Death	1
33	B. BRAUN MEDICAL, INC	VENA TECH LP	04/08/03	JWL	454732	= 459982	Migration (Pulmonary Valve)/Partial Deployment		
34	B. BRAUN MEDICAL, INC	VENA TECH LP	02/18/03	BPV	443744	Migration	Migration (Suprarenal)		
35	B. BRAUN MEDICAL, INC	VENA TECH	02/10/03	BPV	443031	Filter Fracture			
36	B. BRAUN MEDICAL, INC	VENA TECH LP	01/24/03	BPV	439121	Partial Deployment			
37	B. BRAUN MEDICAL, INC	VENA TECH	12/16/02	JWL	433349	Filter embolization	Migration (PA)		
38	B. BRAUN MEDICAL, INC	VENA TECH	12/09/02	JWL	431971	Filter embolization	Migration (Rt Atrium)		
39	B. BRAUN MEDICAL, INC	VENA TECH	11/22/02	BPV	429650	Failed Deployment			
40	B. BRAUN MEDICAL, INC	VENA TECH	11/22/02	JWL	429648	Filter embolization	Migration (PA)		
41	B. BRAUN MEDICAL, INC	VENA TECH LP	05/20/02	JWL	395792	Filter embolization	Migration (Rt Atrium)		
42	B. BRAUN MEDICAL, INC	VENA TECH	05/17/02	JWL	397413	Filter embolization	Migration (PA)		
43	B. BRAUN MEDICAL, INC	VENA TECH LP	05/17/02	JWL	395251	Filter embolization	Migration (Intrahepatic)		
44	B. BRAUN MEDICAL, INC	VENA TECH	05/14/02	JWL	394714	Filter embolization	Migration (PA)		
45	B. BRAUN MEDICAL, INC	VENA TECH	05/07/02	JWL	393904	Filter embolization	Migration (PA)		
46	B. BRAUN MEDICAL, INC	VENA TECH	04/09/02	JWL	388359	Filter embolization	Migration (Pulmonary Valve)		
47	B. BRAUN MEDICAL, INC	1 VENA TECH LP	04/03/02	JWL	385985	Filter embolization	Migration (heart)		
48	B. BRAUN MEDICAL, INC	VENA TECH	02/11/02	BPV	377437	Partial Deployment			

	A	B	C	D	E	F	G	H	I
49	B. BRAUN MEDICAL, INC	VENA TECH	02/11/02	JWL	376310	Filter embolization	Migration (PA)		
50	B. BRAUN MEDICAL, INC	VENA TECH	01/16/02	JWL	371669	Filter embolization	Migration (PA)		
51	B. BRAUN MEDICAL, INC	VENA TECH	01/04/02	BPV	370309	Failed Deployment			
52	B. BRAUN MEDICAL, INC	VENA TECH	09/19/01	JWL	352381	Filter embolization	Migration (Rt Ventricle)		
53	B. BRAUN MEDICAL, INC	VENA TECH	08/23/01	JWL	348753	Filter embolization	Migration (Heart)	Death	1
54	B. BRAUN MEDICAL, INC	VENA TECH LGM VENA C	07/13/01	JWL	341773	= 348753	= 348753		
55	B. BRAUN MEDICAL, INC	VENA TECH	03/22/01	BPV	322186	Failed Deployment			
56	B. BRAUN MEDICAL, INC	VENA TECH	12/15/00	BPV	308891	Partial Deployment			
57	B. BRAUN MEDICAL, INC	VENA TECH	10/02/00	JWL	299202	Other	Sheath Perforation, Detachment of Component(s)		
58	B. BRAUN MEDICAL, INC	VENA TECH	10/02/00	JWL	298961	Failed deployment			
59	B. BRAUN MEDICAL, INC	VENA TECH	07/27/00	JWL	287560	Pulmonary embolism		Death	
60	B. BRAUN MEDICAL, INC	VENA TECH	06/20/00	BPV	282920	Failed Deployment	Deployed Upside-down		
61	B. BRAUN MEDICAL, INC	VEAN TECH	06/20/00	JWL	282203	= 282920			
62	B. BRAUN MEDICAL, INC	VENA TECH	05/04/00	BPV	276511	Failed Deployment	Deployed Upside-down		
63	B. BRAUN MEDICAL, INC	VENA TECH	05/04/00	JWL	276398	Other	Sheath Perforation, Detachment of Component(s)		
64	B. BRAUN MEDICAL, INC	VENA TECH	02/24/00	JWL	264618	Filter embolization	Migration (RA)		
65									
66									
67									
68									
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	A	B	C	D	E	F	G	H	I
1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment
2	15	14	34	10	1	4	9	12	41
3									
4									
5									
6	Company	Device	Date	Source	FDA #	Failure	Notes	Death?	FiltEmb death?
7	BOST SCI	TITANIUM GREENFIELD	9/7/2005	KMJ	633797	Caval Perforation	5 legs prforated caval wall		
8	BOST SCI	GREENFIELD	9/2/2005	KMJ	636383	Migration	at implant		
9	BOST SCI	TITANIUM GREENFIELD	8/31/2005	KMJ	632439	Partial Deployment	Legs crossed		
10	BOST SCI	GREENFIELD 12 FR SS	7/28/2005	KMJ	623432	Guidewire Entrapment			
11	BOST SCI	GREENFIELD 12 FR SS	5/26/2005	KMJ	608237	Migration	to heart		
12	BOST SCI	TITANIUM GREENFIELD	5/26/2005	KMJ	608191	Failed Deployment	Deployed prematurely, pt required surgery		
13	BOST SCI	TITANIUM GREENFIELD	5/26/2005	KMJ	611695	Failed Deployment			
14	BOST SCI	GREENFIELD	5/23/2005	KMJ	609363	Misplaced Deployment	Right iliac vein		
15	BOST SCI	UNKNOWN BRAND NAME	5/16/2005	KMJ	606333	Migration	Rt ventricle then PA & Bard Recovery filter placed		
16	BOST SCI	TITANIUM GREENFIELD	5/13/2005	KMJ	603559	Failed Deployment			
17	BOST SCI	TITANIUM GREENFIELD	5/13/2005	KMJ	604240	Partial Deployment			
18	BOST SCI	GREENFIELD 12 FR SS	5/6/2005	KMJ	601746	Failed Deployment	Deployed outside of pt		
19	BOST SCI	TITANIUM GREENFIELD	4/14/2005	KMJ	592448	Migration	Left pulmonary artery		
20	BOST SCI	GREENFIELD 12 FR SS	4/6/2005	KMJ	588929	Failed Deployment			
21	BOST SCI	GREENFIELD 12 FR SS	4/4/2005	KMJ	589053	Other	Packaging damaged - pin hole		
22	BOST SCI	GREENFIELD 12 FR SS	3/18/2005	KMJ	584666	Misplaced Deployment	Filter depolyed early		
23	BOST SCI	TITANIUM GREENFIELD	3/17/2005	KMJ	585352	Failed Deployment	2 filters failed in same pt		
24	BOST SCI	TITANIUM GREENFIELD	3/17/2005	KMJ	585136	Failed Deployment	3rd worked, pt expired	Death	
25	BOST SCI	TITANIUM GREENFIELD	3/17/2005	KMJ	585153	Partial Deployment			
26	BOST SCI	TITANIUM GREENFIELD	3/16/2005	KMJ	582601	Partial Deployment	Partial Deployment + Migration		
27	BOST SCI	TITANIUM GREENFIELD	3/16/2005	KMJ	582601	Migration	Partial Deployment + Migration		
28	BOST SCI	GREENFIELD 12 FR SS	3/10/2005	KMJ	580668	Misplaced Deployment	Filter depolyed early		
29	BOST SCI	GREENFIELD 12 FR SS	3/2/2005	KMJ	577957	Other	Bleeding		
30	BOST SCI	GREENFIELD 12 FR SS	3/2/2005	KMJ	577953	= 577957	Duplicate of 577957		
31	BOST SCI	GREENFIELD VENA CAVA	2/25/2005	KMJ	577322	Failed Deployment			
32	BOST SCI	TITANIUM GREENFIELD	2/18/2005	KMJ	574621	Partial Deployment			
33	BOST SCI	TITANIUM GREENFIELD	2/18/2005	KMJ	574656	= 574621	Duplicate of 574621		
34	BOST SCI	TITANIUM GREENFIELD	2/18/2005	KMJ	574644	= 574621	Duplicate of 574621		
35	BOST SCI	TITANIUM GREENFIELD	2/18/2005	KMJ	574665	= 574621	Duplicate of 574621		
36	BOST SCI	GREENFIELD 12 FR SS	2/11/2005	KMJ	572385	Failed Deployment	Deployed during pre-op		
37	BOST SCI	FILTERWIRE EX EMBOLI	1/31/2005	KMJ	574156	Failed Deployment			
38	BOST SCI	TITANIUM GREENFIELD	1/26/2005	KMJ	567967	Failed Deployment			
39	BOST SCI	GREENFIELD 12 FR VEN	1/20/2005	KMJ	566637	Partial Deployment	Twisted Legs		
40	BOST SCI	GREENFIELD 12 FR SS	1/7/2005	KMJ	564587	Partial Deployment			
41	BOST SCI	TITANIUM GREENFIELD	1/7/2005	KMJ	564584	Failed Deployment	2 filters failed in same pt		
42	BOST SCI	TITANIUM GREENFIELD	1/7/2005	KMJ	564581	Failed Deployment	(not duplicate)		
43	BOST SCI	GREENFIELD 12 FR SS	1/5/2005	KMJ	563939	Partial Deployment			
44	BOST SCI	GREENFIELD 12FR SS V	12/23/04	BPV		Failed deployment			
45	BOST SCI	GREENFIELD 12 FR SS	12/14/04	BPV		Filter embolization	RV	Death	1
46	BOST SCI	GREENFIELD VENACAVA	12/13/04	BPV		Filter embolization	RA		
47	BOST SCI	TITANIUM GREENFIELD	12/10/04	BPV		Misplaced Deployment			

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48	BOST SCI	GREENFIELD 12 FR SS	12/08/04	BPV		Filter Fracture			
49	BOST SCI	TITANIUM GREENFIELD	12/02/04	BPV		Partial deployment			
50	BOST SCI	GREENFIELD 12 FR SS	11/24/04	BPV		Failed deployment			
51	BOST SCI	GREENFIELD 12 FR SS	11/23/04	BPV	556832	Filter embolization	Heart	Death	1
52	BOST SCI	12 FR TITANIUM GREEN	11/19/04	BPV		Partial deployment			
53	BOST SCI	GREENFIELD 12 FR SS	11/19/04	BPV		Failed deployment			
54	BOST SCI	GREENFIELD 12 FR SS	11/10/04	BPV		Failed deployment			
55	BOST SCI	GREENFIELD 12 FR SS	11/05/04	BPV		Misplaced Deployment			
56	BOST SCI	GREENFIELD 12 FR SS	11/05/04	BPV		Misplaced Deployment			
57	BOST SCI	GREENFIELD VENA CAVA	11/02/04	BPV	553901	Failed deployment			
58	BOST SCI	TITANIUM GREENFIELD	10/22/04	BPV		Failed deployment			
59	BOST SCI	TITANIUM GREENFIELD	10/13/04	BPV		Partial deployment			
60	BOST SCI	TITANIUM GREENFIELD	10/05/04	BPV		Partial deployment			
61	BOST SCI	GREENFIELD 12 FR SS	10/04/04	BPV		Filter embolization	RA		
62	BOST SCI	TITANIUM GREENFIELD	09/27/04	BPV	546086	Partial Deployment	did not open		
63	BOST SCI	GREENFIELD 12 FR SS	09/17/04	JWL	544824	Filter embolization	did not open	Death	1
64	BOST SCI	BOSTON SCIENTIFIC	09/14/04	BPV	544555	Misplaced Deployment			
65	BOST SCI	TITANIUM GREENFIELD	09/02/04	BPV	541936	Partial Deployment	did not open		
66	BOST SCI	GREENFIELD 12 FR SS	08/18/04	BPV	542415	Partial deployment	Crossed Legs		
67	BOST SCI	TITANIUM GREENFIELD	08/13/04	BPV	539718	Partial Deployment			
68	BOST SCI	GREENFIELD 12 FR SS	08/13/04	BPV	539702	Partial deployment	did not open		
69	BOST SCI	GREENFIELD 12 FR SS	07/29/04	BPV	539670	Partial deployment			
70	BOST SCI	GREENFIELD 12 FR SS	07/23/04	BPV	539747	Other	out of box failure		
71	BOST SCI	TITANIUM GREENFIELD	07/22/04	BPV	539743	Partial Deployment			
72	BOST SCI	GREENFIELD 12 FR SS	07/02/04	BPV	533037	Failed Deployment			
73	BOST SCI	GREENFIELD 12 FR SS	06/25/04	BPV	539659	Mislabel	mislabeling		
74	BOST SCI	GREENFIELD 12 FR SS	06/25/04	JWL	539661	= 539659			
75	BOST SCI	GREENFIELD 12 FR SS	06/25/04	JWL	539660	= 539659			
76	BOST SCI	TITANIUM GREENFIELD	06/11/04	BPV	539700	Other	out of box failure		
77	BOST SCI	GREENFIELD 12FR SS V	06/07/04	BPV	539486	Other	out of box failure		
78	BOST SCI	GREENFIELD 12FR SS V	05/28/04	BPV	539436	Other	out of box failure		
79	BOST SCI	GREENFIELD 12 FR SS	05/28/04	JWL	539484	Mislabel			
80	BOST SCI	GREENFIELD 12 FR SS	05/28/04	BPV	539474	Mislabel	mislabeling		
81	BOST SCI	GREENFIELD VENA CAVA	05/28/04	BPV	542507	Filter Fracture			
82	BOST SCI	TITANIUM GREENFIELD	05/26/04	BPV	527119	Failed Deployment	119 and 115 are for 2 GFs		
83	BOST SCI	TITANIUM GREENFIELD	05/26/04	JWL	527115	Failed Deployment	119 and 115 are for 2 GFs		
84	BOST SCI	GREENFIELD FILTER	05/26/04	BPV	528700	Caval Perforation			
85	BOST SCI	TITANIUM GREENFIELD	05/21/04	BPV	539495	Failed Deployment			
86	BOST SCI	TITANIUM GREENFIELD	05/21/04	JWL	539503	= 539495			
87	BOST SCI	TITANIUM GREENFIELD	05/21/04	JWL	539489	= 539495			
88	BOST SCI	GREENFIELD FILTER	05/14/04	BPV	543782	Caval Thrombosis			
89	BOST SCI	GREENFIELD 12 FR SS	05/13/04	BPV	539510	Mislabel	mislabeling		
90	BOST SCI	TITANIUM GREENFIELD	05/05/04	BPV	539523	Failed Deployment			
91	BOST SCI	TITANIUM GREENFIELD	05/05/04	JWL	539517	Failed Deployment	= 539523, but 2 GFs involved		
92	BOST SCI	GREENFIELD 12FR SS	05/04/04	JWL	526935	Migration	did not open		
93	BOST SCI	TITANIUM GREENFIELD	04/23/04	BPV	525696	Partial Deployment			
94	BOST SCI	TITANIUM GREENFIELD	04/16/04	BPV	539490	Partial Deployment	did not open		
95	BOST SCI	GREENFIELD VENA CAVA	04/07/04	BPV	519607	Other			
96	BOST SCI	GREENFIELD 12 FR SS	03/18/04	BPV	535350	Other	out of box failure		
97	BOST SCI	TITANIUM GREENFIELD	03/11/04	BPV	515392	Migration			
98	BOST SCI	GREENFIELD 12FR SS	03/05/04	JWL	514387	Migration	Migration, Did not open		
99	BOST SCI	GREENFIELD 12FR SS V	02/20/04	BPV	525849	Partial Deployment	did not open		

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100	BOST SCI	GREENFIELD 12FR SS V	02/19/04	BPV	524148	Partial Deployment	did not open		
101	BOST SCI	GREENFIELD 12FR SS	02/18/04	BPV	512053	Failed Deployment			
102	BOST SCI	GREENFIELD VENA CAVA	02/06/04	BPV	520736	Partial Deployment			
103	BOST SCI	TITANIUM GREENFIELD	02/05/04	BPV	518401	Misplaced deployment			
104	BOST SCI	GREENFIELD FILTER VC	02/02/04	JWL	510364	Failed Deployment	Dual MDRs with same #		
105	BOST SCI	TITANIUM GREENFIELD	01/28/04	BPV	516462	Failed Deployment	Stuck in Sheath		
106	BOST SCI	GREENFIELD VENA CAVA	01/26/04	BPV	515533	Partial deployment	Crossed Legs		
107	BOST SCI	GREENFIELD FILTER	12/18/03	JWL	502077	Guidewire problem	Guidewire Fracture		
108	BOST SCI	GREENFIELD VENA CAVA	12/11/03	BPV	503459	Partial deployment	Crossed Legs		
109	BOST SCI	GREENFIELD VENA CAVA	12/11/03	JWL	503580	Partial deployment	Not = 503459		
110	BOST SCI	GREENFIELD FILTER	12/09/03	JWL	501625	Failed Deployment			
111	BOST SCI	GREENFIELD FILTER	12/04/03	JWL	501392	Partial Deployment	2 filters in report		
112	BOST SCI	GREENFIELD FILTER	12/04/03	JWL	501392	Misplaced deployment	2 filters in report		
113	BOST SCI	GREENFIELD 12FR SS	12/03/03	BPV	501755	Partial Deployment			
114	BOST SCI	IVC FILTER	11/18/03	BPV	196538	Filter Fracture	Filter Fracture		
115	BOST SCI	TITANIUM GREENFIELD	11/12/03	BPV	496057	Misplaced Deployment			
116	BOST SCI	GREENFIELD 12FR SS V	11/12/03	JWL	494850	Filter embolization	Migration (SVC)		
117	BOST SCI	GREENFIELD FILTER	10/27/03	BPV	497183	Misplaced Deployment	Lot # M001505010		
118	BOST SCI	GREENFIELD 12FR SS	10/08/03	BPV	489386	Other	Guidewire Entrapment		
119	BOST SCI	TITANIUM GREENFIELD	10/01/03	BPV	487086	Partial Deployment			
120	BOST SCI	GREENFIELD 12FR SS	09/24/03	BPV	486210	Partial Deployment			
121	BOST SCI	GREENFIELD 12FR SS V	09/18/03	JWL	485644	Filter embolization	Migration (RA) / Failed Deployment		
122	BOST SCI	GREENFIELD 12FR SS V	09/18/03	JWL	485728	= 485644			
123	BOST SCI	GREENFILED FILTER	08/06/03	JWL	476087	Filter embolization	Migration (Heart)		
124	BOST SCI	GREENFILED FILTER	08/06/03	JWL	476087	Failed deployment	Migration (Heart)		
125	BOST SCI	GREENFIELD 12FR SS	08/01/03	BPV	476017	Misplaced Deployment			
126	BOST SCI	TITANIUM GREENFIELD	07/28/03	BPV	474997	Failed Deployment	Stuck in Sheath		
127	BOST SCI	TITANIUM GREENFIELD	07/23/03	BPV	474037	Partial Deployment			
128	BOST SCI	GREENFIELD 12FR SS V	07/23/03	JWL	473973	Partial deployment			
129	BOST SCI	TITANIUM GREENFIELD	07/21/03	BPV	473510	Filter Fracture	Filter Fracture		
130	BOST SCI	TITANIUM GREENFIELD	06/24/03	JWL	468420	Misplaced Deployment			
131	BOST SCI	GREENFIELD 12FR SS V	06/24/03	BPV	468242	Misplaced Deployment	Deployed Upside-down		
132	BOST SCI	GREENFIELD FILTER	06/04/03	JWL	468679	Partial deployment	Migration (PA)/Partial Deployment, Lot # 50-301 (M001503010)		
133	BOST SCI	GREENFIELD FILTER	06/04/03	JWL	468679	Filter embolization	Migration (PA)/Partial Deployment, Lot # 50-301 (M001503010)		
134	BOST SCI	TITANIUM GREENFIELD	05/22/03	BPV	461796	Partial Deployment			
135	BOST SCI	TITANIUM GREENFIELD	05/20/03	JWL	465562	Partial deployment			
136	BOST SCI	TITANIUM GREENFIELD	05/20/03	BPV	461532	Partial Deployment	2 filters reported, both failed		
137	BOST SCI	TITANIUM GREENFIELD	05/20/03	BPV	461532	Partial Deployment	2 filters reported, both failed		
138	BOST SCI	TITANIUM GREENFIELD	05/20/03	JWL	461540	= 461532			
139	BOST SCI	TITANIUM GREENFIELD	05/19/03	JWL	461154	Partial deployment	Migration (PA)/Partial Deployment		
140	BOST SCI	TITANIUM GREENFIELD	05/19/03	JWL	461154	Filter embolization	Migration (PA)/Partial Deployment		
141	BOST SCI	TITANIUM GREENFIELD	05/15/03	JWL	460859	Partial deployment			
142	BOST SCI	TITANIUM GREENFIELD	05/15/03	BPV	460851	Partial Deployment			
143	BOST SCI	GREENFIELD FILTER	05/15/03	BPV	465690	Partial Deployment			
144	BOST SCI	TITANIUM GREENFIELD	05/15/03	JWL	460856	Misplaced deployment			
145	BOST SCI	GREENFIELD 12FR SS V	05/15/03	JWL	465722	Failed deployment	Unrelated patient death	Death	
146	BOST SCI	TITANIUM GREENFIELD	05/01/03	JWL	457605	Partial deployment			
147	BOST SCI	TITANIUM GREENFIELD	04/14/03	BPV	454257	Failed deployment			
148	BOST SCI	TITANIUM GREENFIELD	04/02/03	BPV	456998	Partial Deployment			
149	BOST SCI	GREENFIELD FILTER	03/14/03	JWL	448053	Caval perforation	1985 procedure		
150	BOST SCI	TITANIUM GREENFIELD	03/07/03	BPV	447589	Failed Deployment	Stuck in Sheath		
151	BOST SCI	TITANIUM GREENFIELD	02/04/03	BPV	440955	Partial Deployment			

	A	B	C	D	E	F	G	H	I
152	BOST SCI	GREENFIELD FILTER	01/28/03	BPV	440287	Misplaced Deployment	Lot # REF 50-300		
153	BOST SCI	GREENFIELD 12FR SS V	01/24/03	BPV	439472	Partial Deployment			
154	BOST SCI	TITANIUM GREENFIELD	01/21/03	BPV	439135	Misplaced Deployment			
155	BOST SCI	TITANIUM GREENFIELD	01/10/03	JWL	436925	Partial deployment	Migration (IVC)/Partial Deployment		
156	BOST SCI	TITANIUM GREENFIELD	01/10/03	JWL	436925	Migration	Migration (IVC)/Partial Deployment		
157	BOST SCI	GREENFIELD FILTER	01/03/03	BPV	436539	Misplaced Deployment	Lot # 50-300 (M001503000)		
158	BOST SCI	GREENFIELD FILTER	12/30/02	BPV	435644	Partial Deployment	Deployed Upside-down		
159	BOST SCI	TITANIUM GREENFIELD	12/13/02	BPV	432990	Partial Deployment			
160	BOST SCI	TITANIUM GREENFIELD	12/13/02	BPV	432985	Partial Deployment			
161	BOST SCI	TITANIUM GREENFIELD	12/13/02	BPV	432854	= 432985	= 432985		
162	BOST SCI	TITANIUM GREENFIELD	12/10/02	BPV	432504	Tilted filter			
163	BOST SCI	GREENFIELD 12FR SS	11/08/02	JWL	426579	Partial deployment	Migration (Rt Atrium)		
164	BOST SCI	GREENFIELD 12FR SS	11/08/02	JWL	426579	Filter embolization	Migration (Rt Atrium)		
165	BOST SCI	GREENFIELD 12FR SS	10/03/02	BPV	420538	Misplaced Deployment			
166	BOST SCI	GREENFIELD 12FR SS	09/25/02	BPV	419024	Partial Deployment			
167	BOST SCI	GREENFIELD 12FR SS	09/16/02	BPV	417286	Partial Deployment			
168	BOST SCI	GREENFIELD FILTER	08/19/02	BPV	413651	Partial Deployment	Lot # 4471005		
169	BOST SCI	GREENFIELD 12FR SS	07/18/02	JWL	406331	Filter embolization	Migration (RA)		
170	BOST SCI	TITANIUM GREENFIELD	07/02/02	BPV	403115	Other	Sheath Penetration of RV	Death	
171	BOST SCI	GREENFIELD 12FR SS	06/25/02	JWL	402548	Partial deployment	Migration (Intrahepatic)/Partial Deployment		
172	BOST SCI	GREENFIELD 12FR SS	06/25/02	JWL	402548	Filter embolization	Migration (Intrahepatic)/Partial Deployment		
173	BOST SCI	TITANIUM GREENFIELD	06/20/02	BPV	400981	Pulmonary Embolism	Partial Deployment/2nd filter placed	Death	
174	BOST SCI	TITANIUM GREENFIELD	06/19/02	JWL	401001	Filter embolization	Migration (PA)/Partial Deployment		
175	BOST SCI	TITANIUM GREENFIELD	06/19/02	JWL	400984	Filter embolization	Migration (PA)		
176	BOST SCI	TITANIUM GREENFIELD	06/12/02	BPV	399412	Partial Deployment			
177	BOST SCI	TITANIUM GREENFIELD	06/12/02	BPV	399383	Partial Deployment			
178	BOST SCI	GREENFIELD 12FR SS	06/11/02	JWL	399256	Partial deployment	Migration (RA)		
179	BOST SCI	GREENFIELD 12FR SS	06/11/02	JWL	399256	Filter embolization	Migration (RA)		
180	BOST SCI	GREENFIELD 12FR SS	06/06/02	BPV	398839	Guidewire Entrapment			
181	BOST SCI	TITANIUM GREENFIELD	05/22/02	BPV	396548	Misplaced Deployment			
182	BOST SCI	GREENFIELD FILTER	04/18/02	BPV	390358	Partial Deployment			
183	BOST SCI	TITANIUM GREENFIELD	03/29/02	BPV	386124	Partial Deployment			
184	BOST SCI	GREENFIELD FILTER	03/07/02	BPV	447100	Failed Deployment	Lot # 4003871		
185	BOST SCI	GREENFIELD 12FR SS	02/28/02	JWL	380010	Filter embolization	Migration (heart)		
186	BOST SCI	TITANIUM GREENFIELD	02/21/02	BPV	378601	Partial Deployment			
187	BOST SCI	GREENFIELD 12FR SS	02/07/02	BPV	376120	Partial Deployment			
188	BOST SCI	GREENFIELD 12FR SS	01/22/02	BPV	373981	Partial Deployment			
189	BOST SCI	TITANIUM GREENFIELD	01/14/02	BPV	371481	Partial Deployment			
190	BOST SCI	TITANIUM GREENFIELD	12/11/01	JWL	365521	Filter embolization	Migration (femoral to SVC)		
191	BOST SCI	GREENFIELD 12FR SS	12/07/01	BPV	365290	Misplaced Deployment			
192	BOST SCI	TITANIUM GREENFIELD	12/05/01	BPV	364809	Partial Deployment			
193	BOST SCI	GREENFIELD 12FR SS	11/19/01	BPV	362587	Partial Deployment			
194	BOST SCI	GREENFIELD 12FR SS	11/08/01	BPV	360285	Partial Deployment			
195	BOST SCI	TITANIUM GREENFIELD	10/22/01	BPV	358289	Partial Deployment			
196	BOST SCI	GREENFIELD 12FR SS	10/22/01	BPV	358209	Partial Deployment			
197	BOST SCI	GREENFIELD FILTER	10/18/01	BPV	357280	Partial Deployment	Lot # 3945902		
198	BOST SCI	GREENFIELD 12FR SS	10/18/01	BPV	357289	Partial Deployment			
199	BOST SCI	GREENFIELD 12FR SS	10/18/01	JWL	356485	Filter embolization	Migration (RA, then RV)		
200	BOST SCI	GREENFIELD 12FR SS	10/18/01	JWL	356469	Filter embolization	Migration (PA)		
201	BOST SCI	GREENFIELD 12FR SS	10/17/01	BPV	356371	Partial Deployment			
202	BOST SCI	GREENFIELD 12FR SS	10/02/01	BPV	354459	Partial Deployment			
203	BOST SCI	TITANIUM GREENFIELD	09/17/01	BPV	352539	Partial Deployment			

	A	B	C	D	E	F	G	H	I
204	BOST SCI	TITANIUM GREENFIELD	09/06/01	BPV	350588	Partial Deployment			
205	BOST SCI	GREENFIELD FILTER	08/24/01	BPV	349045	Pulmonary Embolism	Failed Deployment	Death	
206	BOST SCI	GREENFIELD FILTER	08/24/01	BPV	349045	Failed deployment	Failed Deployment		
207	BOST SCI	GREENFIELD 12FR SS	08/16/01	BPV	347797	Partial Deployment			
208	BOST SCI	GREENFIELD 12FR SS	08/16/01	BPV	347784	Partial Deployment			
209	BOST SCI	GREENFIELD 12FR SS	08/15/01	BPV	347656	Partial Deployment			
210	BOST SCI	GREENFIELD 12FR SS	08/09/01	BPV	346828	Misplaced Deployment			
211	BOST SCI	TITANIUM GREENFIELD	07/25/01	BPV	343949	Partial Deployment			
212	BOST SCI	GREENFIELD 12FR SS	07/25/01	BPV	343617	Partial Deployment			
213	BOST SCI	TITANIUM GREENFIELD	07/25/01	BPV	343960	Misplaced Deployment			
214	BOST SCI	GREENFIELD 12FR SS	07/25/01	BPV	343617	Filter embolization	right atrium		
215	BOST SCI	GREENFIELD 12FR SS	07/16/01	BPV	342639	Misplaced Deployment			
216	BOST SCI	GREENFIELD 12FR SS	07/11/01	BPV	343143	Misplaced Deployment			
217	BOST SCI	GREENFIELD FILTER	07/09/01	BPV	341615	Misplaced Deployment			
218	BOST SCI	GREENFIELD 12FR SS	06/25/01	BPV	339558	Partial Deployment			
219	BOST SCI	GREENFIELD 12FR SS	06/22/01	BPV	339250	Partial Deployment			
220	BOST SCI	TITANIUM GREENFIELD	06/22/01	BPV	338684	Misplaced Deployment			
221	BOST SCI	GREENFIELD 12FR SS	06/22/01	BPV	339221	Misplaced Deployment	Deployed Upside-down		
222	BOST SCI	GREENFIELD 12FR SS	06/13/01	BPV	337789	Partial Deployment			
223	BOST SCI	GREENFIELD 12FR SS	06/06/01	JWL	336419	Other	Guidewire pulled filter into iliac		
224	BOST SCI	TITANIUM GREENFIELD	06/06/01	JWL	336293	Filter embolization	Migration (PA)		
225	BOST SCI	GREENFIELD FILTER	05/17/01	BPV	333639	Misplaced Deployment			
226	BOST SCI	GREENFIELD 12FR SS	04/24/01	BPV	329109	Partial Deployment			
227	BOST SCI	TITANIUM CREENFIELD	04/20/01	BPV	328313	Filter fracture	Filter Fracture		
228	BOST SCI	GREENFIELD 12FR SS	04/10/01	BPV	325919	Caval Perforation		Death	
229	BOST SCI	GREENFIELD 12FR SS	04/06/01	JWL	324695	Filter embolization	Migration (Rt atrium)/GW entrapment		
230	BOST SCI	TITANIUM GREENFIELD	03/16/01	BPV	321369	Partial Deployment			
231	BOST SCI	GREENFIELD 12FR SS	03/09/01	BPV	320035	Caval Perforation			
232	BOST SCI	TITANIUM GREENFIELD	02/28/01	JWL	318266	Partial deployment			
233	BOST SCI	GREENFIELD 12FR SS	02/20/01	BPV	317528	Partial Deployment			
234	BOST SCI	GREENFIELD 12FR SS	02/14/01	BPV	316104	Partial Deployment			
235	BOST SCI	GREENFIELD 12FR SS	02/09/01	JWL	315274	Partial deployment	Migration (Cephalad)		
236	BOST SCI	GREENFIELD FILTER	02/09/01	JWL	315264	Partial deployment	Migration (Cephalad)		
237	BOST SCI	GREENFIELD 12FR SS	02/09/01	JWL	315274	Migration	Migration (Cephalad)		
238	BOST SCI	GREENFIELD FILTER	02/09/01	JWL	315264	Migration	Migration (Cephalad)		
239	BOST SCI	GREENFIELD 12FR SS	02/08/01	BPV	315122	Guidewire Entrapment			
240	BOST SCI	GREENFIELD FILTER	02/02/01	BPV	314449	Caval Perforation		Death	
241	BOST SCI	GREENFIELD 12FR SS	01/25/01	BPV	313979	Partial Deployment			
242	BOST SCI	GREENFIELD 12FR SS	01/17/01	BPV	312972	Partial Deployment			
243	BOST SCI	TITANIUM GREENFIELD	01/16/01	BPV	312588	Partial Deployment			
244	BOST SCI	GREENFIELD 12FR SS	01/10/01	BPV	312130	Partial Deployment			
245	BOST SCI	GREENFIELD 12FR SS	01/10/01	BPV	312124	Partial Deployment			
246	BOST SCI	GREENFIELD FILTER	01/05/01	JWL	311496	Filter embolization	Migration (Rt Atrium)		
247	BOST SCI	GREENFIELD 12FR SS	01/04/01	JWL	311046	Partial deployment	Migration (Heart)		
248	BOST SCI	GREENFIELD 12FR SS	01/04/01	JWL	311046	Filter embolization	Migration (Heart)		
249	BOST SCI	TITANIUM GREENFIELD	12/20/00	BPV	309973	Partial Deployment			
250	BOST SCI	GREENFIELD 12FR SS	12/19/00	BPV	309310	Guidewire Entrapment			
251	BOST SCI	TITANIUM GREENFIELD	12/08/00	BPV	308044	Partial Deployment			
252	BOST SCI	GREENFIELD 12FR SS	12/07/00	BPV	307740	Partial Deployment			
253	BOST SCI	GREENFIELD 12FR SS	12/07/00	BPV	307729	Filter fracture	Filter Fracture		
254	BOST SCI	GREENFIELD 12FR SS	12/05/00	BPV	307673	Partial Deployment			
255	BOST SCI	GREENFIELD 12FR SS	11/27/00	JWL	306489	Migration	Migration (Rt Atrium)/Guidewire Entrapment		

	A	B	C	D	E	F	G	H	I
256	BOST SCI	GREENFIELD FILTER	11/27/00	JWL	306487	Migration	Migration (Iliac)		
257	BOST SCI	GREENFIELD FILTER	11/17/00	BPV	305247	Misplaced Deployment	Deployed Upside-down		
258	BOST SCI	GREENFIELD 12FR SS	11/10/00	BPV	304539	Partial Deployment			
259	BOST SCI	GREENFIELD 12FR SS	11/01/00	JWL	302808	Filter embolization	Migration (PA)/Partial Deployment		
260	BOST SCI	GREENFIELD 12FR SS	10/31/00	BPV	302837	Partial Deployment			
261	BOST SCI	GREENFIELD 24FR SS V	10/27/00	JWL	301962	Filter fracture	Filter Fracture		
262	BOST SCI	GREENFIELD FILTER	10/24/00	BPV	301521	Caval Perforation	Central Line	Death	
263	BOST SCI	GREENFIELD 12FR SS	10/03/00	BPV	299224	Guidewire Entrapment			
264	BOST SCI	GREENFIELD 12FR SS	09/27/00	BPV	298479	Partial Deployment			
265	BOST SCI	TITANIUM GREENFIELD	09/27/00	BPV	298485	Misplaced Deployment			
266	BOST SCI	TITANIUM GREENFIELD	09/19/00	BPV	296859	Partial Deployment			
267	BOST SCI	TITANIUM GREENFIELD	09/19/00	BPV	296855	Partial Deployment			
268	BOST SCI	TITANIUM GREENFIELD	09/12/00	BPV	295758	Filter fracture	Filter Fracture		
269	BOST SCI	TITANIUM GREENFIELD	09/05/00	BPV	294486	Partial Deployment			
270	BOST SCI	GREENFIELD 12FR SS	09/05/00	BPV	294217	Partial Deployment			
271	BOST SCI	GREENFIELD 12FR SS	09/05/00	BPV	294495	Misplaced Deployment	Deployed Upside-down		
272	BOST SCI	TITANIUM GREENFIELD	09/01/00	BPV	294503	Caval Perforation			
273	BOST SCI	GREENFIELD 12FR SS	08/23/00	BPV	292346	Guidewire Entrapment			
274	BOST SCI	GREENFIELD 12FR SS	08/14/00	BPV	290202	Partial Deployment			
275	BOST SCI	TITANIUM GREENFIELD	08/02/00	BPV	288431	Misplaced Deployment			
276	BOST SCI	GREENFIELD 12FR SS	08/02/00	BPV	288163	Failed Deployment			
277	BOST SCI	GREENFIELD FILTER	07/26/00	BPV	287223	Filter fracture			
278	BOST SCI	GREENFIELD 12FR SS	07/18/00	BPV	286578	Partial Deployment			
279	BOST SCI	GREENFIELD 12FR SS	07/18/00	BPV	286574	Partial Deployment			
280	BOST SCI	GREENFIELD 12FR SS	07/18/00	BPV	286451	Misplaced Deployment			
281	BOST SCI	GREENFIELD 12FR SS	07/18/00	BPV	286446	Misplaced Deployment			
282	BOST SCI	TITANIUM GREENFIELD	06/21/00	BPV	283348	Partial Deployment			
283	BOST SCI	TITANIUM GREENFIELD	06/21/00	BPV	282884	Partial Deployment			
284	BOST SCI	GREENFIELD 12FR SS	06/21/00	BPV	283341	Partial Deployment			
285	BOST SCI	GREENFIELD 12FR SS	06/21/00	BPV	283262	Guidewire Entrapment			
286	BOST SCI	GREENFIELD FILTER	06/12/00	BPV	282506	Partial Deployment			
287	BOST SCI	GREENFIELD 12FR SS	06/12/00	BPV	281960	Failed Deployment			
288	BOST SCI	GREENFIELD 12FR SS	06/07/00	BPV	281518	Misplaced Deployment			
289	BOST SCI	TITANIUM GREENFIELD	06/06/00	JWL	280475	Filter embolization	Migration (PA)		
290	BOST SCI	TITANIUM GREENFIELD	05/30/00	BPV	280085	Pulmonary Embolism	Caval Thrombosis	Death	
291	BOST SCI	TITANIUM GREENFIELD	05/30/00	BPV	280454	Partial Deployment			
292	BOST SCI	GREENFIELD 12FR SS	05/30/00	BPV	280457	Partial Deployment			
293	BOST SCI	GREENFIELD 12FR SS	05/30/00	BPV	280460	Misplaced Deployment			
294	BOST SCI	GREENFIELD 12FR SS	05/30/00	BPV	280458	Misplaced Deployment			
295	BOST SCI	GREENFIELD 12FR SS	05/30/00	BPV	280457	Migration	into suprarenal IVC		
296	BOST SCI	TITANIUM GREENFIELD	05/30/00	JWL	280287	Filter embolization	PA		
297	BOST SCI	TITANIUM GREENFIELD	05/30/00	JWL	280281	= 280287	PA		
298	BOST SCI	GREENFIELD 12FR SS	05/23/00	BPV	279283	Partial Deployment			
299	BOST SCI	GREENFIELD 12FR SS	05/18/00	BPV	278823	Partial Deployment			
300	BOST SCI	TITANIUM GREENFIELD	05/16/00	JWL	278192	Partial deployment			
301	BOST SCI	TITANIUM GREENFIELD	05/16/00	JWL	277714	Filter embolization	Right atrium		
302	BOST SCI	TITANIUM GREENFIELD	05/16/00	BPV	277510	Caval Perforation		Death	
303	BOST SCI	TITANIUM GREENFIELD	05/15/00	BPV	278198	Misplaced Deployment	Guidewire Fracture		
304	BOST SCI	TITANIUM GREENFIELD	05/15/00	BPV	278203	Failed Deployment			
305	BOST SCI	TITANIUM GREENFIELD	04/25/00	BPV	275192	Partial Deployment			
306	BOST SCI	GREENFIELD FILTER	04/25/00	JWL	275896	Filter embolization	Migration (Rt Atrium)		
307	BOST SCI	GREENFIELD FILTER	04/13/00	JWL	273523	Other		Death	

	A	B	C	D	E	F	G	H	I
308	BOST SCI	GREENFIELD FILTER	04/05/00	BPV	272392	Pulmonary Embolism		Death	
309	BOST SCI	GREENFIELD 12FR SS	03/30/00	BPV	271789	Partial Deployment			
310	BOST SCI	GREENFIELD 12FR SS	03/23/00	BPV	270582	Guidewire entrapment			
311	BOST SCI	GREENFIELD 12FR SS	03/23/00	BPV	270582	Caval perforation			
312	BOST SCI	GREENFIELD 12FR SS	03/13/00	BPV	269355	Partial Deployment			
313	BOST SCI	GREENFIELD FILTER	02/29/00	JWL	266358	Misplaced Deployment			
314	BOST SCI	TITANIUM GREENFIELD	02/24/00	BPV	264706	Partial Deployment			
315	BOST SCI	TITANIUM GREENFIELD	02/15/00	JWL	262672	Filter embolization	Migration (Rt Atrium)/Partial Deployment		
316	BOST SCI	GREENFIELD 12FR SS	02/08/00	JWL	261703	Filter embolization			
317	BOST SCI	GREENFIELD 12FR SS	02/07/00	BPV	261685	Guidewire entrapment			
318	BOST SCI	GREENFIELD 12FR SS	02/03/00	BPV	261346	Partial Deployment			
319	BOST SCI	TITANIUM GREENFIELD	01/24/00	BPV	260104	Partial Deployment			
320	BOST SCI	GREENFIELD 12FR SS	01/24/00	BPV	259996	Partial Deployment			
321	BOST SCI	GREENFIELD 12FR SS	01/20/00	BPV	260088	Misplaced deployment	Right atrium		
322	BOST SCI	GREENFIELD 12FR SS	01/20/00	BPV	260088	Filter embolization	Right atrium		
323	BOST SCI	TITANIUM GREENFIELD	01/19/00	BPV	259451	Partial Deployment			
324	BOST SCI	GREENFIELD 12FR SS	01/13/00	BPV	258915	Partial Deployment			
325	BOST SCI	GREENFIELD FILTER	01/11/00	BPV	258378	Partial deployment			
326	BOST SCI	GREENFIELD FILTER	01/11/00	BPV	258378	Filter embolization	right atrium		
327	BOST SCI	TITANIUM GREENFIELD	01/06/00	BPV	258202	Partial Deployment			
328	BOST SCI	GREENFIELD 12FR SS	01/06/00	BPV	258192	Guidewire entrapment			
329	BOST SCI	GREENFIELD 12FR SS	01/06/00	BPV	257774	Guidewire entrapment			
330	BOST SCI	GREENFIELD 12FR SS	01/05/00	JWL	257468	Guidewire entrapment			

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment	Failed Deployment	Tilted Filter	Other
2	1	1	1	11	0	1	7	0	6	0	3	0	0
3													
4													
5													
6	Company	Device	Date	Source	FDA #	Failure	Location	Death?	FiltEmb death?	0			
7	COOK	GIANTURCO-ROEHM BIRD	7/28/2005	KMJ	623050	Caval perforation							
8	COOK	GIANTURCO-ROEHM BIRD	7/21/2005	KMJ	622309	Caval perforation	2 Fractures + Perforation						
9	COOK	GIANTURCO-ROEHM BIRD	7/21/2005	KMJ	622309	Filter Fracture	2 Fractures + Perforation						
10	COOK, INC.	GIANTURCO-ROEHM BIRD	3/31/2005	KMJ	586889	Filter Fracture							
11	COOK, INC.	GIANTUROO-ROEHM BIRD	3/18/2005	KMJ	582927	Caval perforation							
12	COOK, INC.	GIANTURCO-ROEHM BIRD	10/15/04	BPV	548688	Failed deployment							
13	COOK, INC.	GIANTURCO-ROEHM BIRD	06/16/04	BPV	529846	Filter Fracture							
14	COOK, INC.	GIANTURCO-ROEHM BIRD	02/05/04	JWL	518393	Filter fracture							
15	COOK, INC.	GIANTURCO-ROEHM BIRD	11/25/03	JWL	497692	Caval perforation	Into liver and aorta						
16	COOK, INC.	GIANTURCO-ROEHM BIRD	10/22/03	BPV	490724	Caval Perforation							
17	COOK, INC.	GIANTURCO-ROEHM BIRD	10/13/03	BPV	488685	Migration	Partial Deployment						
18	COOK, INC.	GIANTURCO-ROEHM BIRD	08/29/03	BPV	481488	Filter Fracture	Filter Fracture						
19	COOK, INC.	GIANTURCO-ROEHM BIRD	08/05/03	BPV	475747	Filter Fracture	Filter Fracture						
20	COOK, INC.	GIANTURCO-ROEHM BIRD	05/08/03	JWL	458274	Caval perforation	IVC perforation						
21	COOK, INC.	GIANTURCO-ROEHM BIRD	12/03/02	BPV	430523	Caval Perforation							
22	COOK, INC.	GIANTURCO-ROEHM BIRD	08/29/02	BPV	413286	Pulmonary Embolism	Bariatric surgery	Death					
23	COOK, INC.	GIANTURCO-ROEHM BIRD	08/27/02	JWL	412818	Caval perforation	Into duodenum, fistula						
24	COOK, INC.	GIANTURCO-ROEHM BIRD	08/15/02	JWL	410525	= 410382							
25	COOK, INC.	GIANTURCO-ROEHM BIRD	08/15/02	BPV	410382	Caval Perforation							
26	COOK, INC.	GIANTURCO-ROEHM BIRD	06/21/02	BPV	400758	Caval Perforation							
27	COOK, INC.	GIANTURCO-ROEHM BIRD	05/01/02	JWL	392091	= 400758							
28	COOK, INC.	GIANTURCO-ROEHM BIRD	12/05/01	JWL	364147	= 347774	Migration (Rt Atrium)						
29	COOK, INC.	BIRDSNEST	08/06/01	JWL	347774	Filter embolization	Heart						
30	COOK, INC.	GIANTURCO-ROEHM BIRD	06/18/01	BPV	338167	Filter Fracture	Filter Fracture						
31	COOK, INC.	GIANTURCO-ROEHM BIRD	04/16/01	JWL	327101	Failed deployment							
32	COOK, INC.	GIANTURCO-ROEHM BIRD	02/26/01	BPV	317376	Misplaced Deployment							
33	COOK, INC.	GIANTURCO-ROEHM BIRD	09/18/00	BPV	296447	Failed Deployment	DeliverySystem						
34	COOK, INC.	GIANTURCO-ROEHM BIRD	04/24/00	BPV	274704	Misplaced Deployment							
35	COOK, INC.	GIANTURCO-ROEHM BIRD	04/18/00	BPV	273790	Misplaced Deployment							
36	COOK, INC.	GIANTURCO-ROEHM BIRD	03/30/00	BPV	271421	Misplaced Deployment							
37	COOK, INC.	GIANTURCO-ROEHM BIRD	03/23/00	BPV	270408	Misplaced Deployment							
38	COOK, INC.	GIANTURCO-ROEHM BIRD	03/20/00	BPV	270018	Caval Perforation							
39	COOK, INC.	GIANTURCO-ROEHM BIRD	02/11/00	BPV	261910	Misplaced Deployment							
40													
41													
42													
43													
44													
45													
46													
47													
48													
49													

	A	B	C	D	E	F	G	H	I	J	K
1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment	Failed Deployment
2	7	6	8	10	2	2	0	0	5	17	13
3											
4											
5											
6	Company	Device	Date	Source	FDA #	Failure	Notes	Death?	FiltEmb death?	2	
7	COOK	GUNTHER TULIP VENA C	9/23/2005	KMJ	636844	Failed deployment					
8	COOK	GUNTHER TULIP VENA C	9/9/2005	KMJ	634010	Migration	at implant				
9	COOK	GUNTHER TULIP	9/9/2005	KMJ	634005	Failed deployment					
10	COOK	GUNTHER TULIP VENA C	9/7/2005	KMJ	633458	Failed deployment	vessel pierced?				
11	COOK	GUNTHER TULIP VENA C	7/27/2005	KMJ	622800	Other	bled profusely from access site				
12	COOK	GUNTHER TULIP VENA C	7/27/2005	KMJ	622818	Partial deployment					
13	COOK, INC.	GUNTHER TULIP VENA C	6/15/2005	KMJ	613925	Detachment of Component(s)	Guidewaire & sheath in heart	Death			
14	COOK, INC.	GUNTHER TULIP VENA C	5/27/2005	KMJ	608107	Caval Perforation					
15	COOK, INC.	GUNTHER TULIP VENA C	4/27/2005	KMJ	597905	Partial deployment					
16	COOK, INC.	GUNTHER TULIP VENA C	4/8/2005	KMJ	589113	Partial deployment					
17	COOK, INC.	GUNTHER TULIP VENA C	4/5/2005	KMJ	587808	Pulmonary embolism	?				
18	COOK, INC.	GUNTHER TULIP VENA C	4/1/2005	KMJ	587043	Partial deployment	"opposed itself to the cava wall"				
19	COOK, INC.	GUNTHER TULIP VENA C	3/25/2005	KMJ	584933	Tilted Filter	Autopsy results pending	Death			
20	COOK, INC.	GUNTHER TULIP VENA C	3/4/2005	KMJ	578055	Misplaced Deployment					
21	COOK, INC.	GUNTHER TULIP VENA C	3/4/2005	KMJ	578055	Caval Perforation					
22	COOK, INC.	UNKNOWN BRAND NAME	2/25/2005	KMJ	576360	Other	Unknown injury				
23	COOK, INC.	GUNTHER TULIP VENA C	2/24/2005	KMJ	575851	Partial deployment	Legs did not fully open				
24	COOK, INC.	GUNTHER TULIP VENA C	2/18/2005	KMJ	574713	Partial deployment	Legs did not fully open				
25	COOK, INC.	GUNTHER TULIP VENA C	2/18/2005	KMJ	574732	Partial deployment	Filter opened asymmetrically				
26	COOK, INC.	GUNTHER TULIP VENA C	2/18/2005	KMJ	574702	Partial deployment	Legs did not fully open				
27	COOK, INC.	GUNTHER TULIP VENA C	2/4/2005	KMJ	570330	Partial deployment	Legs did not fully open				
28	COOK, INC.	GUNTHER TULIP VENA C	1/27/2005	KMJ	542855	Failed deployment					
29	COOK, INC.	GUNTHER TULIP VENA C	10/21/04	BPV	550370	Caval Thrombosis		Death			
30	COOK, INC.	GUNTHER TULIP VENA C	10/15/04	BPV	548881	Failed deployment					
31	COOK, INC.	GUNTHER TULIP VENA C	10/08/04	BPV	547688	Caval Perforation					
32	COOK, INC.	GUNTHER TULIP VENA C	8/26/2004	BPV	540694	Partial deployment	crossed legs				
33	COOK, INC.	GUNTHER TULIP VENA C	7/23/2004	BPV	535670	Caval Thrombosis					
34	COOK, INC.	GUNTHER TULIP VENA C	6/3/2004	BPV	534699	Caval Perforation					
35	COOK, INC.	GUNTHER TULIP	05/07/04	BPV	525493	Other	Defective Part				
36	COOK, INC.	GUNTHER TULIP	05/07/04	BPV	524016	Other	Broken Snare				
37	COOK, INC.	GUNTHER TULIP VENA C	5/7/2004	BPV	524016	Other	retrieval failure				
38	COOK, INC.	GUNTHER TULIP	04/22/04	BPV	521847	Tilted Filter					
39	COOK, INC.	GUNTHER TULIP	04/14/04	BPV	520682	Failed deployment					
40	COOK, INC.	GUNTHER TULIP	04/08/04	BPV	519818	Migration					
41	COOK, INC.	GUNTHER TULIP	04/08/04	BPV	519818	Caval Perforation					
42	COOK, INC.	GUNTHER TULIP	03/22/04	BPV	517127	Migration	Migration (Suprarenal)				
43	COOK, INC.	GUNTHER TULIP	03/19/04	BPV	516823	Caval Perforation					
44	COOK, INC.	GUNTHER TULIP VENA C	02/11/04	JWL	510942	Failed deployment					
45	COOK, INC.	GUNTHER TULIP	02/11/04	BPV	510932	Failed Deployment	Filter Did Not Open				
46	COOK, INC.	GUNTHER TULIP VENA C	12/29/03	JWL	503753	Filter embolization	Rt Atrium				
47	COOK, INC.	GUNTHER TULIP VENA C	11/20/03	BPV	497932	Partial Deployment					
48	COOK, INC.	GUNTHER TULIP VENA C	10/28/03	BPV	491788	Partial Deployment					
49	COOK, INC.	GUNTHER TULIP VENA C	10/14/03	BPV	488736	Failed Deployment					

	A	B	C	D	E	F	G	H	I	J	K
50	COOK, INC.	GUNTHER TULIP	07/29/03	BPV	474088	Tilted Filter					
51	COOK, INC.	GUNTHER TULIP	06/06/03	JWL	464216	Partial deployment	Migration (Rt Atrium)				
52	COOK, INC.	GUNTHER TULIP	06/06/03	JWL	464216	Filter embolization	Migration (Rt Atrium)				
53	COOK, INC.	GUNTHER TULIP	04/09/03	BPV	452767	Caval Perforation					
54	COOK, INC.	GUNTHER TULIP	03/25/03	BPV	449607	Migration	Migration (Suprarenal)				
55	COOK, INC.	GUNTHER TULIP	03/12/03	BPV	447612	Partial deployment	Legs Twisted				
56	COOK, INC.	GUNTHER TULIP	03/12/03	BPV	447595	Partial deployment	Legs Twisted				
57	COOK, INC.	GUNTHER TULIP	02/24/03	BPV	444069	Partial deployment					
58	COOK, INC.	GUNTHER TULIP	02/24/03	JWL	444069	Filter embolization	Migration (Rt Atrium)/Failed Moving				
59	COOK, INC.	GUNTHER TULIP	01/30/03	BPV	440084	Pulmonary embolism	Migration (Suprarenal)				
60	COOK, INC.	GUNTHER TULIP	01/30/03	BPV	440084	Migration	Migration (Suprarenal)				
61	COOK, INC.	GUNTHER TULIP	01/10/03	BPV	436917	Tilted filter					
62	COOK, INC.	GUNTHER TULIP	12/17/02	JWL	432928	Filter embolization	Migration (Heart)/Failed Moving				
63	COOK, INC.	GUNTHER TULIP	11/25/02	BPV	429105	Misplaced Deployment					
64	COOK, INC.	GUNTHER TULIP	09/16/02	BPV	416378	Failed Deployment					
65	COOK, INC.	GUNTHER TULIP	08/27/02	BPV	412806	Partial deployment	Legs Twisted				
66	COOK, INC.	GUNTHER TULIP VENA C	07/30/02	JWL	407673	Migration					
67	COOK, INC.	FUNTHER TULIP VENA C	07/25/02	BPV	406758	Failed deployment					
68	COOK, INC.	GUNTHER TULIP	06/21/02	JWL	400782	Failed deployment					
69	COOK, INC.	GUNTHER TULIP	06/21/02	JWL	400782	Filter embolization	Heart	Death	1		
70	COOK, INC.	GUNTHER TULIP	06/12/02	BPV	398939	Caval Perforation		Death			
71	COOK, INC.	GUNTHER TULIP	05/30/02	JWL	397217	Failed deployment	Heart				
72	COOK, INC.	GUNTHER TULIP	05/30/02	JWL	397217	Filter embolization	Heart	Death	1		
73	COOK, INC.	GUNTHER TULIP	05/16/02	JWL	394030	Misplaced deployment	Heart				
74	COOK, INC.	GUNTHER TULIP	05/16/02	JWL	394030	Filter embolization	Heart				
75	COOK, INC.	GUNTHER TULIP	05/02/02	BPV	391390	Caval Perforation		Death			
76	COOK, INC.	GUNTHER TULIP	04/29/02	BPV	390356	Misplaced Deployment					
77	COOK, INC.	GUNTHER TULIP	03/13/02	BPV	381305	Filter embolization	right atrium				
78	COOK, INC.	GUNTHER TULIP	03/13/02	BPV	381305	Misplaced Deployment					
79	COOK, INC.	GUNTHER TULIP VENA C	02/27/02	JWL	378605	Other					
80	COOK, INC.	GUNTHER TULIP	09/28/01	BPV	353598	Caval perforation					
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1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment
2	29	10	19	19	62	8	18	0	0	15
3										
4										
5										
6	Company	Device	Date	Source	FDA #	Failure	Notes	Death?	FiltEmb death?	9
7	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	9/8/2005	KMJ	634320	Failed Deployment				
8	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	9/7/2005	KMJ	634304	Filter Fracture				
9	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	8/30/2005	KMJ	633190	Caval Thrombosis				
10	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	8/25/2005	KMJ	632044	Failed Deployment				
11	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	8/22/2005	KMJ	629334	Caval Thrombosis				
12	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	8/12/2005	KMJ	627058	Pulmonary embolism		Death		
13	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	8/5/2005	KMJ	624909	Caval Thrombosis				
14	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	7/18/2005	KMJ	622017	Pulmonary embolism		Death		
15	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	7/18/2005	KMJ	622058	Failed Deployment				
16	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT F	7/14/2005	KMJ	621741	Migration	to diaphragm			
17	CORDIS EUROPA, N.V.	TRAEASE PERMANENT VE	6/23/2005	KMJ	617473	Filter embolization				
18	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	6/10/2005	KMJ	613267	Filter embolization	Morbidly obese pt			
19	CORDIS EUROPA, N.V.	TRAPEASE UNK FILTER	6/2/2005	KMJ	611082	Other	laceration 2cm distal to filter	Death		
20	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	4/29/2005	KMJ	598106	Filter embolization	IVC fully thrombosed	Death	1	
21	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	4/27/2005	KMJ	597684	Failed Deployment				
22	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	4/22/2005	KMJ	595176	Other	Retroperitoneal bleed			
23	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	4/8/2005	KMJ	590441	Migration	Suprarenal			
24	CORDIS EUROPA, N.V.	TRAPEASE UNK FILTER	3/21/2005	KMJ	584046	Caval Thrombosis				
25	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	3/18/2005	KMJ	583561	Failed Deployment				
26	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	3/16/2005	KMJ	582555	Caval Perforation		Death		
27	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	3/10/2005	KMJ	581289	Caval Thrombosis				
28	CORDIS EUROPA, N.V.	TRAPEASE UNK FILTER	3/7/2005	KMJ	579168	Filter embolization	Heart			
29	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	3/3/2005	KMJ	581668	Filter Fracture				
30	CORDIS EUROPA, N.V.	TRAPEASE UNKNOWN FIL	2/28/2005	KMJ	577727	Filter embolization	Pulmonary artery	Death	1	
31	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	2/25/2005	KMJ	580543	Filter Fracture				
32	CORDIS EUROPA, N.V.	TRAPEASE PERMANET VE	2/25/2005	KMJ	576690	Filter Fracture				
33	CORDIS EUROPA, N.V.	TRAPEASE UNK FILTER	2/24/2005	KMJ	576373	Caval Perforation	fracture punctured aorta	Death		
34	CORDIS EUROPA, N.V.	TRAPEASE UNK FILTER	2/24/2005	KMJ	576373	Filter Fracture	fracture punctured aorta			
35	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT F	2/22/2005	KMJ	574994	Caval Perforation	Perforation + Migration			
36	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT F	2/22/2005	KMJ	574994	Migration	Perforation + Migration	Death		
37	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	2/22/2005	KMJ	577648	Filter Fracture				
38	CORDIS EUROPA, N.V.	TRAPEASE VENA CAVA F	2/15/2005	KMJ	553138	Filter embolization	autopsy pending	Death	1	
39	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	2/11/2005	KMJ	573024	Failed Deployment				
40	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	2/11/2005	KMJ	576426	Failed Deployment				
41	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	2/11/2005	KMJ	572540	Pulmonary embolism	PE & Fracture (same pt)			
42	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	1/28/2005	KMJ	581062	Filter Fracture	PE & Fracture (same pt)			
43	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	1/21/2005	KMJ	583297	Failed Deployment				
44	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	1/5/2005	BPV	567329	Partial Deployment				
45	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/22/04	BPV	556636	Filter embolization	Tricuspid Valve			
46	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/17/04	BPV	555653	Other				
47	CORDIS CORPORATION	TRAPEASE IVC FILTER	11/01/04	BPV	558588	Filter Fracture	punctured aorta	Death		
48	CORDIS CORPORATION	TRAPEZE FILTER	10/28/04	BPV	561521	Caval Thrombosis				
49	CORDIS CORPORATION	TRAPEASE PERMANENT V	8/12/2004	BPV	538721	Caval Thrombosis				
50	CORDIS CORPORATION	TRAPEASE PERMANENT V	8/12/2004	BPV	538729	Caval Thrombosis				
51	CORDIS CORPORATION	TRAPEASE PERMANENT V	8/12/2004	BPV	538833	Caval Thrombosis				
52	CORDIS CORPORATION	TRAPEASE FILTER	7/16/2004	BPV	535731	Caval Perforation		Death		
53	CORDIS CORPORATION	TRAPEASE FILTER	7/16/2004	BPV	535731	Caval thrombosis				
54	CORDIS CORPORATION	TRAPEASE PERMANENT V	7/13/2004	BPV	534357	Failed Deployment				
55	CORDIS CORPORATION	TRAPEASE PERMANENT V	7/13/2004	BPV	534359	Filter embolization	heart	Death	1	
56	CORDIS CORPORATION	TRAP-EASE	7/1/2004	BPV	533876	Other	PE	Death		

	A	B	C	D	E	F	G	H	I	J
6	Company	Device	Date	Source	FDA #	Failure	Notes	Death?	FiltEmb death?	9
57	CORDIS CORPORATION	TRAPEASE PERMANENT V	6/28/2004	BPV	532518	Filter embolization	PA			
58	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/18/04	BPV	530718	Caval Perforation	Lumbar(?)			
59	CORDIS CORPORATION	TRAPEASE VENA CAVA F	4/30/2004	BPV	525715	Filter embolization	SVC (BARIATRIC)			
60	CORDIS CORPORATION	TRAPEASE VENA CAVA F	4/30/2004	BPV	525715	Failed deployment	SVC (BARIATRIC)			
61	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/28/04	BPV	522537	Filter Fracture				
62	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/28/04	BPV	522537	Pulmonary embolism				
63	CORDIS CORPORATION	TRAPEASE PERMANENT V	03/01/04	BPV	514509	Caval Perforation				
64	CORDIS CORPORATION	TRAPEASE PERMANENT V	02/23/04	BPV	512770	Failed Deployment	Filter Did Not Open			
65	CORDIS CORPORATION	TRAPEASE PERMANENT V	2/4/2004	BPV	525165	Filter Fracture				
66	CORDIS EUROPA, N.V.	TRAPEASE PERMANENT V	2/2/2004	JWL	509799	= 510344				
67	CORDIS CORPORATION	TRAPEASE PERMANENT V	02/02/04	BPV	510344	Caval Thrombosis				
68	CORDIS CORPORATION	TRAPEASE PERMANENT V	01/20/04	BPV	513000	=513006				
69	CORDIS CORPORATION	TRAPEASE PERMANENT V	1/20/2004	BPV	513006	Other	Strut Bent			
70	CORDIS CORPORATION	TRAPEASE PERMANENT V	01/09/04	BPV	505640	Filter embolization	Rt Ventricle	Death	1	
71	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/19/03	BPV	501966	Other	BARIATRIC			
72	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/19/03	BPV	501994	Migration	Migration			
73	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/05/03	BPV	502004	Filter Fracture				
74	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/20/03	BPV	498583	Filter Fracture				
75	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/14/03	BPV	495497	Filter embolization	Migration (Rt Atrium)			
76	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/11/03	BPV	495600	Filter embolization	Migration (Rt Atrium)			
77	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/05/03	BPV	493714	Caval Thrombosis				
78	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/31/03	BPV	493717	Caval Thrombosis				
79	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/31/03	BPV	494160	Filter Fracture				
80	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/29/03	BPV	492611	Caval Thrombosis				
81	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/27/03	BPV	491452	Caval Perforation		Death		
82	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/27/03	BPV	492352	Caval Perforation				
83	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/08/03	BPV	489092	Filter embolization	Migration (SVC)	Death	1	
84	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/08/03	BPV	490223	Caval Perforation				
85	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/15/03	BPV	487678	Caval Thrombosis				
86	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/15/03	BPV	487682	Caval Thrombosis				
87	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/10/03	BPV	483427	Partial Deployment				
88	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/12/03	BPV	478085	Filter Fracture				
89	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/07/03	BPV	477020	Filter Fracture				
90	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/06/03	BPV	476182	Caval Thrombosis		Death		
91	CORDIS CORPORATION	TRAPEASE PERMENENT V	08/01/03	BPV	475628	= 471736	Migration (PA)			
92	CORDIS CORPORATION	TRAPEASE PERMANENT V	07/23/03	BPV	473871	Partial Deployment				
93	CORDIS CORPORATION	TRAPEASE PERMANENT V	07/15/03	BPV	471736	Filter embolization	Migration (PA)	Death	1	
94	CORDIS CORPORATION	TRAPEASE	06/27/03	BPV	473028	= 471736	Migration (PA)			
95	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/18/03	BPV	466546	Caval Perforation		Death		
96	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/17/03	BPV	466036	Partial Deployment				
97	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/28/03	BPV	456208	Caval Thrombosis				
98	CORDIS CORPORATION	TRAPEASE PERMANENT V	03/20/03	BPV	449105	Other	MW1026472			
99	CORDIS CORPORATION	TRAPEASE	02/28/03	BPV	445805	= 445807				
100	CORDIS CORPORATION	TRAPEASE PERMANENT V	02/28/03	BPV	445807	Caval Thrombosis				
101	CORDIS CORPORATION	TRAPEASE	02/28/03	BPV	445967	= 445807				
102	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/19/02	BPV	434341	Caval Thrombosis				
103	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/26/02	BPV	429685	Caval Thrombosis		Death		
104	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/26/02	BPV	430340	Caval Thrombosis				
105	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/31/02	BPV	425265	Caval Perforation				
106	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/23/02	BPV	424103	Failed Deployment	Stuck in Sheath			
107	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/23/02	BPV	424106	Other				
108	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/15/02	BPV	422521	Caval Thrombosis				
109	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/12/02	BPV	422969	Caval Perforation				
110	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/04/02	BPV	421028	Caval Thrombosis				
111	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/04/02	BPV	421045	= 421028				
112	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/04/02	BPV	421059	= 421028				
113	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/04/02	BPV	421132	= 421028				

	A	B	C	D	E	F	G	H	I	J
6	Company	Device	Date	Source	FDA #	Failure	Notes	Death?	FiltEmb death?	9
114	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/04/02	BPV	421155	= 421028				
115	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/04/02	BPV	421155	Caval perforation				
116	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/03/02	BPV	420438	Migration	Migration (Suprarenal)			
117	CORDIS CORPORATION	TRAPEASE	10/02/02	BPV	419378	Migration	Migration (Suprarenal)			
118	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/01/02	BPV	419891	Filter Fracture				
119	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/02/02	BPV	414795	= 414801				
120	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/02/02	BPV	414801	Caval Thrombosis		Death		
121	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/02/02	BPV	414807	Caval Thrombosis				
122	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/02/02	BPV	414830	Caval Thrombosis				
123	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/30/02	BPV	414493	Partial Deployment				
124	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/30/02	BPV	414493	Migration				
125	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/23/02	BPV	412485	Pulmonary embolism	Bariatric use	Death		
126	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/09/02	BPV	409571	Migration	Migration			
127	CORDIS CORPORATION	TRAPEASE PERMANENT V	07/03/02	BPV	402872	Failed deployment		Death		
128	CORDIS CORPORATION	TRAPEASE PERMANENT V	07/01/02	BPV	403107	Partial Deployment				
129	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/20/02	BPV	400720	Other	Delivery sheath failure			
130	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/10/02	BPV	398630	Caval Thrombosis				
131	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/10/02	BPV	398778	Caval thrombosis	Inferred from MDR			
132	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/03/02	BPV	397536	Caval Thrombosis				
133	CORDIS CORPORATION	TRAPEASE PERMANENT V	05/29/02	BPV	396809	Caval Perforation				
134	CORDIS CORPORATION	TRAPEASE PERMANENT V	05/29/02	BPV	396812	Caval Perforation				
135	CORDIS CORPORATION	TRAPEASE PERMANENT V	03/25/02	BPV	384621	Caval Thrombosis				
136	CORDIS CORPORATION	TRAPEASE PERMANENT V	03/19/02	BPV	382807	Caval Thrombosis				
137	CORDIS CORPORATION	TRAPEASE	03/19/02	BPV	382812	Caval Thrombosis				
138	CORDIS CORPORATION	TRAPEASE	03/19/02	BPV	382814	Caval Thrombosis				
139	CORDIS CORPORATION	TRAPEASE	03/19/02	BPV	382828	Caval Thrombosis				
140	CORDIS CORPORATION	TRAPEASE	03/19/02	BPV	382832	Caval Thrombosis				
141	CORDIS CORPORATION	TRAPEASE PERMANENT V	03/08/02	BPV	381138	Other	Letter of Concern			
142	CORDIS CORPORATION	TRAPEASE PERMANENT V	01/30/02	BPV	374525	Migration	Migration (Suprarenal)			
143	CORDIS CORPORATION	TRAPEASE PERMANENT V	01/30/02	BPV	374525	Other	Renal vein thrombosis			
144	CORDIS CORPORATION	TRAPEASE PERMANENT V	01/30/02	BPV	374620	Filter Fracture				
145	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/04/01	BPV	363383	Caval perforation				
146	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/01/01	BPV	359223	Failed Deployment	Stuck in Sheath			

	A	B	C	D	E	F	G	H	I	J
6	Company	Device	Date	Source	FDA #	Failure	Notes	Death?	FiltEmb death?	9
147	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/17/01	JWL	356045	Filter embolization	Migration (Rt Atrium)	Death	1	
148	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/27/01	BPV	353318	Caval Thrombosis				
149	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/19/01	BPV	352239	Caval Thrombosis				
150	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/10/01	BPV	351038	Partial Deployment				
151	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/04/01	BPV	349862	Caval Thrombosis				
152	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/21/01	JWL	347962	Filter embolization	Migration (Rt Atrium)			
153	CORDIS CORPORATION	TRAPEASE PERMANENT V	08/13/01	BPV	347020	Failed Deployment	Stuck in Sheath			
154	CORDIS CORPORATION	TRAPEASE PERMANENT V	07/19/01	BPV	343267	Failed Deployment	Stuck in Sheath			
155	CORDIS CORPORATION	TRAPEASE PERMANENT V	07/18/01	BPV	342518	Caval Thrombosis				
156	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/28/01	JWL	339597	Filter embolization	Caval thromb. less impt	Death	1	
157	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/28/01	JWL	339597	Caval thrombosis				
158	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/21/01	BPV	338397	Caval Thrombosis				
159	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/14/01	BPV	337233	Caval Thrombosis				
160	CORDIS CORPORATION	TRAPEASE PERMANENT V	06/05/01	BPV	336244	Failed deployment				
161	CORDIS CORPORATION	TRAPEASE PERMANENT V	05/24/01	BPV	334952	Partial Deployment				
162	CORDIS CORPORATION	TRAPEASE PERMANENT V	05/21/01	BPV	333898	Caval Thrombosis				
163	CORDIS CORPORATION	TRAPEASE PERMANENT V	05/21/01	BPV	334342	Partial Deployment				
164	CORDIS CORPORATION	TRAPEASE PERMANENT V	05/18/01	BPV	333677	Caval Thrombosis				
165	CORDIS CORPORATION	TRAPEASE PERMANENT V	05/01/01	BPV	329850	Caval Thrombosis				
166	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/27/01	BPV	329103	Caval Perforation	Sheath Perforation	Death		
167	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/27/01	BPV	329285	Caval Thrombosis				
168	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/27/01	BPV	329295	Partial Deployment				
169	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/12/01	BPV	326474	Caval Thrombosis				
170	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/12/01	BPV	326483	Caval Thrombosis				
171	CORDIS CORPORATION	TRAPEASE	04/12/01	BPV	326487	Caval Thrombosis				
172	CORDIS CORPORATION	TRAPEASE	04/12/01	BPV	326512	= Europe report				
173	CORDIS CORPORATION	TRAPEASE PERMANENT V	04/02/01	BPV	323875	Caval Thrombosis	also had PE	Death		
174	CORDIS CORPORATION	TRAPEASE PERMANENT V	03/27/01	BPV	322621	Caval Thrombosis		Death		
175	CORDIS CORPORATION	TRAPEASE PERMANENT V	03/09/01	JWL	319700	Filter embolization	Migration (Rt Atrium)			
176	CORDIS CORPORATION	TRAPEASE PERMANENT V	03/05/01	BPV	318548	Filter Fracture				
177	CORDIS CORPORATION	TRAPEASE PERMANENT V	02/16/01	BPV	316469	Migration	Migration (just below renals)			
178	CORDIS CORPORATION	TRAPEASE PERMANENT V	02/16/01	BPV	316469	Caval thrombosis	Migration (just below renals)			
179	CORDIS CORPORATION	TRAPEASE PERMANENT V	02/08/01	BPV	315103	Failed deployment				
180	CORDIS CORPORATION	TRAPEASE PERMANENT V	02/07/01	BPV	315120	Caval Thrombosis				
181	CORDIS CORPORATION	TRAPEASE PERMANENT V	02/01/01	BPV	314825	Partial Deployment				
182	CORDIS CORPORATION	TRAPEASE PERMANENT V	01/22/01	BPV	313140	Caval Perforation				
183	CORDIS CORPORATION	TRAPEASE PERMANENT V	01/03/01	BPV	311191	Partial Deployment				
184	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/28/00	BPV	310050	Pulmonary Embolism				
185	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/20/00	BPV	309224	Pulmonary Embolism		Death		
186	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/20/00	BPV	309224	Caval Thrombosis				
187	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/14/00	BPV	308776	Caval Thrombosis				
188	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/07/00	BPV	307581	Caval Thrombosis				
189	CORDIS CORPORATION	TRAPEASE PERMANENT V	12/04/00	BPV	307481	Partial Deployment				
190	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/27/00	BPV	306053	Caval Thrombosis				
191	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/27/00	BPV	306060	Caval Thrombosis				
192	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/27/00	BPV	306449	Caval Thrombosis				
193	CORDIS CORPORATION	TRAPEASE PERMANANT V	11/13/00	BPV	303960	Caval Perforation				
194	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/10/00	BPV	304534	Caval Thrombosis				
195	CORDIS CORPORATION	TRAPEASE PERMANENT V	11/02/00	BPV	303408	Partial Deployment				
196	CORDIS CORPORATION	TRAPEASE PERMANENT V	10/24/00	BPV	301346	Caval Thrombosis				
197	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/25/00	BPV	297255	Partial Deployment				
198	CORDIS CORPORATION	TRAPEASE PERMANENT V	09/15/00	BPV	296521	Pulmonary Embolism				
199										
200										
201										
202										
203										

	A	B	C	D	E	F	G	H	I	J	K
1	Death	Migration	Filter Embolization	Caval Perforation	Caval Thrombosis	Pulmonary Embolism	Filter Fracture	Guidewire Entrapment	Misplaced Deployment	Partial Deployment	Failed Deployment
2	3	4	0	0	4	4	8	0	2	0	3
3											
4											
5											
6	Company	Device	Date	Source	FDA #	Failure	Location	Death?	FiltEmb death?	0	
7	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	9/9/2005	KMJ	634317	Filter Fracture	Migration + Fracture				
8	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	9/9/2005	KMJ	634317	Migration	Migration + Fracture				
9	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	8/11/2005	KMJ	627216	Pulmonary embolism					
10	CORDIS EUROPA, N.V.	OPTEASE RETRIEVABLE	8/24/2005	KMJ	638499	Failed Deployment					
11	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	5/11/2005	KMJ	602961	Other	Removal unsuccessful				
12	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	5/2/2005	KMJ	599023	Filter Embolism	Caval occlusion, had to amputate both feet				
13	CORDIS EUROPA, N.V. .	OPTEASE VENA CAVA FI	4/25/2005	KMJ	596511	Filter Fracture					
14	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	4/22/2005	KMJ	596517	Filter Fracture					
15	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	3/17/2005	KMJ	543467	Filter Fracture					
16	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	2/25/2005	KMJ	585849	Filter Fracture					
17	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	2/24/2005	KMJ	576016	Caval Thrombosis					
18	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	2/22/2005	KMJ	575121	Migration					
19	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	2/22/2005	KMJ	577683	Filter Fracture					
20	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	2/11/2005	KMJ	576420	Failed Deployment					
21	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	2/7/2005	KMJ	574565	Migration					
22	CORDIS EUROPA, N.V.	OPTEASE VENA CAVA FI	1/6/2005	KMJ	564520	Pulmonary embolism					
23	CORDIS CORPORATION	OPTEASE VENA CAVA FI	12/22/04	BPV	561545	Caval Thrombosis					
24	CORDIS CORPORATION	OPTEASE VENA CAVA FI	12/14/04	BPV	559903	Other	Patient in trial	Death			
25	CORDIS CORPORATION	OPTEASE VENA CAVA FI	10/18/04	BPV	549704	Filter Fracture					
26	CORDIS CORPORATION	OPTEASE VENA CAVA FI	9/10/2004	BPV	543467	Caval Thrombosis					
27	CORDIS CORPORATION	OPTEASE VENA CAVA FI	6/25/2004	BPV	531999	Misplaced deployment	deployed upside down				
28	CORDIS CORPORATION	OPTEASE FILTER	06/08/04	BPV	529157	Other					
29	CORDIS CORPORATION	OPTEASE FILTER	04/15/04	BPV	521015	Misplaced Deployment					
30	CORDIS CORPORATION	OPTEASE FILTER	04/01/04	BPV	518862	Migration	Migration (Iliac)				
31	CORDIS CORPORATION	OPTEASE FILTER	03/24/04	BPV	517808	Pulmonary embolism	Presumptive	Death			
32	CORDIS CORPORATION	OPTEASE FILTER	02/27/04	BPV	513869	Caval Thrombosis	Bi-Iliac				
33	CORDIS CORPORATION	OPTEASE VENA CAVA FI	2/5/2004	BPV	521333	Filter Fracture					
34	CORDIS CORPORATION	OPTEASE FILTER	02/02/04	BPV	509857	Failed Deployment	Deployed Upside-Down				
35	CORDIS CORPORATION	OPTEASE FILTER	12/10/03	BPV	500240	Pulmonary embolism	Presumptive	Death			
36											
37											
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EXHIBIT 6

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

(FILED UNDER SEAL)

EXHIBIT 7

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

(FILED UNDER SEAL)

EXHIBIT 8

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

(FILED UNDER SEAL)

EXHIBIT 9

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

(FILED UNDER SEAL)

EXHIBIT 10

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

(FILED UNDER SEAL)

EXHIBIT 11

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS)
LIABILITY LITIGATION) MD No.: 02641
_____)

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

CONTINUED VIDEOTAPED DEPOSITION OF CHAD MICHAEL MODRA

Phoenix, Arizona
January 20, 2016
9:01 a.m.

REPORTED BY:
Robin L. B. Osterode, RPR, CSR
AZ Certified Reporter No. 50695

need -- you can take MAUDE completely out of the picture. You don't even need MAUDE, if the -- for the company to determine a rate comparison between all of these complications, for all of its IVC devices, in comparing those rates to the Simon Nitinol Filter. Right?

A. I'm not --

Q. You don't understand the question?

A. No, I didn't under --

Q. You just told me you don't need MAUDE for you to do internal rates of complications, because you have actual sales. You have actual complaints.

A. Correct.

Q. All right. Take MAUDE. We don't need MAUDE. MAUDE could burn. And that's true for the Simon Nitinol Filter through and including the Denali Filter?

A. That's true.

Q. You have all that data, sales data, you have complaint data?

A. Yes, we have --

Q. And you can do internal rate comparison, using your own data, that you know is more reliable than what's in MAUDE. Right?

A. With -- yeah, with some caveats because we

EXHIBIT 12

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

IN THE UNITED STATES DISTRICT COURT
IN THE SOUTHERN DISTRICT OF FLORIDA

SAMANTHA BOULDRY, ELUA HUFF, SANDRA LORENZ, and JANET ROBERTS, on behalf of themselves and the class of all others similarly situated,	
Plaintiffs,	Case No: 12-80951-CIV-ROSENBAUM
vs.	
C. R. BARD, INC., a corporation of the State of New Jersey, and BARD PERIPHERAL VASCULAR, INC., a corporation of the State of Arizona, et al.,	
Defendants.	

CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

DEPOSITION OF ROBERT MICHAEL CARR, JR.

Phoenix, Arizona
April 17, 2013

BY: KARLA M. MARTIN, RPR, CSR
Arizona CR No. 50485

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Q. All right. Number two, the distraught customer wants to know what system is in place to monitor complication events. Is he or she entitled to have an answer to that question?

A. I believe I already answered that. Yes. I think that would be something that could be communicated.

Q. Number three, the distraught customer wants to know what is the official complication rate of the G2 filter compared to other filters. Is he or she entitled to have an answer to that question?

A. No. It's speculation.

Q. Why is it speculation?

A. Because I don't know the rates of other filters.

Q. Would Bard at least provide this distraught customer, this physician, with its official complication rate of the G2 as of August 2008?

A. No. It's confidential information.

Q. Okay. Number four, this distraught customer wanted to know why are the fractures reported on Maude similar. Is he or she entitled to have an answer to that question?

MR. BORANIAN: I relodge my objections. It's calling for speculation, improper form.

MR. JOHNSON: Your objection is preserved.

A. I don't understand the question, so I don't know